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FINAL SUBMISSION OF  
THE CANADIAN RED CROSS SOCIETY

TO THE  
COMMISSION OF INQUIRY ON THE  
BLOOD SYSTEM IN CANADA

December 6, 1996

Volume 1 of 4



The Canadian Red Cross Society



**COMMISSION OF INQUIRY ON THE  
BLOOD SYSTEM IN CANADA**

**THE CANADIAN RED CROSS SOCIETY  
SUBMISSIONS**

**VOLUME I**

**PART I and PART II**

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# COMMISSION OF INQUIRY ON THE BLOOD SYSTEM IN CANADA

## THE CANADIAN RED CROSS SOCIETY SUBMISSIONS

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## PREFACE

The following three volumes comprise an organized chronology documenting the issues, events and decisions that shaped the blood system during the early-to-mid 1980's. A dissection and analysis of policy decisions and actions taken over a decade ago involving a myriad of players is a difficult exercise. The documentary record is often incomplete, ambiguous, or vague. Even when the record is reasonably complete and apparently straightforward, interpreting its meaning demands the reconstruction of the historical context, without which no comments or decisions can be properly understood.

A thorough review of the events of the past is necessary to shape the direction of the future. To fully appreciate the response of the medical, scientific and blood-banking community to the problems of AIDS and hepatitis, it is necessary to understand and analyze the decisions of this era in the context of the evolution of knowledge. This historical overview must not fall prey to the trap of hindsight. Current knowledge and testimony about past events may be refined by years of subconscious reinterpretation in light of new knowledge. Difficulties that confronted decision-makers at the time do not appear so compelling when reviewed in conjunction with present knowledge. While to ignore history is to ignore the lessons to be learned from it, judging those involved in the making of that history, with the benefit of hindsight, carries with it the real danger of injustice to those who were doing their best with the knowledge they had at the time.

Drs. Zuck and Eyster, in their response to the 1996 Institute Of Medicine's, *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking* commented:

Although blood bankers and those who treat persons with hemophilia are supportive of most of the recommendations of the Report, the manner in which the analysis was conducted and some of the general conclusions that were reached appear flawed. The flaws may reflect the deficiencies in the process by which the Committee gathered data more than any bias on the part of its members themselves. The Report may accurately reflect the testimony heard, but it is biased by the committee's acceptance as fact the opinions of critics who claim the AIDS epidemic was mismanaged by the blood-collecting agencies, professional organizations, hemophilia organizations, and the federal



government. Countervailing views on the various issues are ignored or incompletely discussed. Much testimony was taken from the victims of the transfusion-associated AIDS epidemic. Reliance seems to have been placed upon hindsight testimony (taken 10 years after the events), rather than on documentation of what was known at the time when events unfolded. The Report states that "[t]he Committee's charge did not include the development of assertions about what should have been done at the time," yet that is precisely what was done.

These comments address just a few of the misconceptions we perceive in the Report. They are based on our understanding of the state of knowledge - or ignorance - at the time that decisions about the safety of the blood supply were made. If we are to avert future threats to the blood supply from emerging infectious diseases, a goal that is universally embraced, we must learn the lessons the past can teach us, as painful as they may be. However, the hazards of judging history in hindsight should be avoided. Neither allegations nor opinions should be accepted as facts without critical examination and without placement in the context of contemporary knowledge; to accept a lesser standard does a great injustice to all who were touched by this tragedy.<sup>1</sup>

In considering the actions of the Canadian Red Cross Society during the 1980's one Medical Director had this to say:

Could we have done more? Could the Red Cross Society not have done more? The answer is, in retrospect, yes, we probably could. The Canadian Red Cross Society is an organization devoted to the highest principles of humanitarianism. It is, unhappily, staffed by human beings, since angels are not available.<sup>2</sup>

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<sup>1</sup> Ex. 1299, "Blood Safety Decisions, 1982-1986: perceptions and misconceptions," by T. Zuck and M. Eyster; in *Transfusion*

<sup>2</sup> Dr. MacKay, Medical Director New Brunswick Centre, pp. 12125-12126.



I. CONTEXT FOR UNDERSTANDING THE CRCS RESPONSE TO THE THREAT OF AIDS

A. STRUCTURE OF THE CANADIAN BLOOD SYSTEM

1. The Canadian blood system is an evolving entity. While some of the elements and procedures in existence during the 1980's continue to be in force today, there have been numerous changes made and the blood system continues to evolve. The following submissions, however, relate to the system as it existed and the events as they unfolded during the 1980's.
2. While the Canadian public inexorably links the Canadian Red Cross Society (hereinafter referred to as "CRCS") with the Canadian blood system, the CRCS is one of several actors in a complex system. The CRCS operated a national blood program comprised of blood donor recruitment, collection, processing of blood components, and distribution. Other integral features of this multifaceted system, such as policy development, regulation, fractionation of blood derivatives, and clinical treatment, were the purview of other parties. In order to appreciate the response of the Canadian blood system to the threat of Acquired Immune Deficiency Syndrome (hereinafter referred to as "AIDS") and Hepatitis C, it is a pre-requisite to understand the basic nature of this system.
3. The national blood program operated by the CRCS was (and continues to be) considered among the best in the world.<sup>3</sup> As the system was multifaceted, and not operated by a single organization, the policies and goals of the various actors were occasionally incompatible.

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<sup>3</sup> *Evidence of George Weber, Secretary General, Federation of National Red Cross/ Red Crescent Societies, pp. 40412-40413;*

*Evidence of Dr. Pinkerton, Physician at Sunnybrook Hospital Blood Bank, pp. 3796-3797; and*

*Evidence of Dr. Francis Shepherd, NAC AIDS Panel, pp. 24632-24634.*



The only policy guidelines for the blood system in the 1980's were four principles adopted by the Ministers of Health in the 1970's. These principles were:

Principle #1

*To protect the voluntary donor system by enhancing the opportunities of Canadians to voluntarily donate a gift for society's general benefit and by responsibly managing that resource.*

Principle #2

*To ensure self-sufficiency of blood products by reducing Canada's dependence on foreign sources of blood products supply, particularly those that rely on purchased plasma for raw material.*

Principle #3

*To ensure gratuity of blood products by reinforcing the Canadian tradition whereby no payment is made for donation of blood and/or plasma and no specific charge is made to recipients of blood and blood products.*

Principle #4

*That a Canadian non-profit policy be maintained and that any charge to recover more than the real cost of producing a blood fractionation product for Canadians in Canada should be considered profit.<sup>4</sup>*

4. The first three principles were proposed by the Honourable M. Marc Lalonde who was the federal Minister of Health, in response to a CRCS proposal for the construction and operation of a fractionation plant. These principles were subsequently adopted by the provincial Ministers of Health. The fourth principle was proposed by the Ad Hoc Committee of Deputy Ministers on Blood and Blood Products in 1979, and subsequently adopted by the Conference of Health Ministers.<sup>5</sup>

5. These principles were ambiguous in nature and provided a mere skeletal framework to assist in governing the Canadian blood system. Other than the above guidelines,

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<sup>4</sup> Ex. 736, Tab 7, p. 103 (*Canadian Blood Committee Draft Terms of Reference, Commentary by the Canadian Red Cross Society, Appendix VI "Detailed Analysis on the Draft Terms of Reference of the Canadian Blood Committee"*, dated April 12, 1982).

<sup>5</sup> Ex. 736, Tab 7, pp. 11-13 (*CRCS Commentary on the CBC Draft Terms of Reference, April 12, 1982*).



Canada had no national blood policy which could be referenced when the disparate elements of the blood system conflicted.

6. The absence of a national blood policy did not go unnoticed by the actors in the system. Principally, the CRCS lobbied the federal and provincial Ministers of Health for the creation of such a policy. Notwithstanding their entreaties and efforts, Canada, to this date, does not have a national blood policy.<sup>6</sup>

7. The absence of an overriding policy made it difficult for the various actors to understand clearly which party had precisely what role and responsibility:

DR. PERRAULT: Well, inherently the blood system had many components, and we have discussed this during the past few weeks. The government being one part. The hospitals, the patients being another part, and the Red Cross being the collective processor and distributor of blood products.

This was basically a system that had several players and the health care system of Canada being a provincial responsibility, the decision back in 1974 to completely fund the BTS,...was a provincial decision. And the framework under which this operated was not established. And coupled with that you had the federal regulatory aspects.

So essentially what you had was a national system for blood delivery in a system that was strictly provincial.

MR. CHERNIAK: And...was there anybody that was equipped or able to take a true leadership role?

DR. PERRAULT: Not with that particular set up, because the policy -- we are sitting at the top of a tree where all parties could refer to, then it would have been simple on the funding issues, and as Chatfield points out, the blood policy be established that would define standards for blood product utilization, for information on all aspects of the blood product market, and ensure that Canada's resources are managed efficiently.

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<sup>6</sup> The efforts of the CRCS to obtain a national policy are discussed at Section II, *infra*.



Now the experience that I was exposed to during that period of time with some of the civil servants who were groping with the same issue is the fact that the civil servants who are very well trained to administer acts or pieces of legislation, be it provincial or federal, did not have anything similar to work with dealing with blood.<sup>7</sup>

8. By way of contrast, the United States, unlike Canada, had a national blood policy which identified the roles and responsibilities of the various actors in its system. This enabled members of the American system, including blood banks, public health authorities and regulators, to better understand the responsibilities, the accountabilities, and the limits of their authority. In 1985, the U.S. Office of Technology Assessment reviewed the effectiveness of the American blood policy. It noted that:

The "National Blood Policy" which has guided the development of our blood services complex over the past decade was not codified in law but was an expression of commitment, backed by specific activities that used the Policy as a general guiding principle. The establishment of a Blood Program in the National Heart, Lung and Blood Institute, represented by the NHLBI's Division of Blood Diseases and Resources, and the strengthening of safety and efficacy standards through establishment of a blood products division in the Office of Biologics Research and Review (previously the Bureau of Biologics) provided the primary instruments through which Federal policy could be formulated, implemented and maintained. In the initial years of the NBP, there was a direct fiscal relationship between the Federal and private sectors through major support of the private sector body, the American Blood Commission, which was established in order to provide for continued, decentralized, management of blood resources. Federal interest at the central policy level within the Department of Health and Human Services slowly faded away, leaving the Blood Division at NHLBI and the Office of Biologics Research and Review as the primary Federal participants in continuing with the objectives of the National Blood Policy, and improving the biomedical base of blood resources and the safety and effectiveness of blood products.<sup>8</sup>

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<sup>7</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 30595-30596.

<sup>8</sup> Ex. 728-B (*Plasma Quarterly*, Volume 7, Number 4, Fall 1985, "OTA Report: Blood Policy and Technology", Part III, p.213).



9. Comparisons with the blood system in the United States are not entirely appropriate, given the dissimilar elements between the two systems.<sup>9</sup> Comparisons with other national blood programs are impossible due to the paucity of evidence called in respect of these systems at the Inquiry. Other countries which have a national blood policy find it fundamental to the operation of their blood system.<sup>10</sup>

1) Actors within the Canadian Blood System

a) Composition of the Canadian Blood System

10. For ease of reference, the various elements of the blood system can be defined as follows:

- i) Recruitment;
- ii) Donation and Collection;
- iii) Processing;
- iv) Distribution;
- v) Clinical usage;
- vi) Policy;
- vii) Regulation; and
- viii) Funding.

As will be described below, responsibility within the Canadian blood system was somewhat fluid, which was a consequence of the absence of clearly-defined rules and responsibilities.

11. The CRCS is a non-profit humanitarian organization. Accordingly, it does not have a profit motive in the blood system. Decisions made in the operation of the blood program

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<sup>9</sup> See Section I A (2) for an overview of the American system.

<sup>10</sup> Evidence of George Weber, Secretary General, Federation of National Red Cross/ Red Crescent Societies, pp. 40446-40447.



were based upon requirements for blood and blood derivatives, scientific knowledge, the availability of funding, and, where they existed, policy and regulations set down by the federal and provincial governments.

i. **Recruitment**

12. Recruitment of blood and plasma donors was undertaken by the CRCS through its Blood Donor Recruitment Program (hereinafter referred to as "BDR"). While BDR was part of the CRCS national blood program, until 1992 it was operated by the provincial divisions of the CRCS.<sup>11</sup>

13. BDR was directly accountable to divisional commissioners, who were permanent staff members of the divisions. Divisions were operated on a provincial basis and divisional commissioners reported to provincial governing boards of the CRCS.<sup>12</sup> This contrasted with the Blood Transfusion Service (hereinafter referred to as "BTS") which was accountable to the National Commissioner (later Secretary General) who reported to the National Board of Directors of the CRCS.

ii. **Donation and Collection**

14. The volunteer blood and plasma donors are the nucleus of the Canadian blood system. They donated 100% of Canada's whole blood requirements and approximately 50% of

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<sup>11</sup> *Evidence of George Weber, Secretary General, Federation of National Red Cross/ Red Crescent Societies*, pp. 40612-40613.

<sup>12</sup> *Evidence of George Weber, Secretary General, Federation of National Red Cross/ Red Crescent Societies*, p. 40577.



Canada's requirements for plasma fractionation.<sup>13</sup> The emphasis on volunteer donors was highlighted by the first ministerial principle which called for an all-volunteer blood system.<sup>14</sup>

15. The donation and collection service in Canada was operated as part of the CRCS blood program managed by the BTS. Blood and plasma were collected from seventeen regions across Canada. Each region had its own CRCS blood centre. The day-to-day operations of each of these centres were overseen by a regional medical director. The medical director, in turn, reported to the Assistant National Director of the BTS at the National Office, who, in turn, reported to the National Director of the BTS. Although this national collection service worked on a regional basis, any region could be called upon to alleviate a shortage in another region in times of emergency.<sup>15</sup>

### iii. Processing

16. Blood was separated into components by the CRCS. Blood products were fractionated by private biological companies in Canada and the United States.

17. The choice of fractionator, the quantity of Canadian fresh frozen plasma shipped to that fractionator and the quantity of supplementary plasma products purchased by the CRCS were not determined by one body.

18. The Ministries of Health for the provinces, through the Canadian Blood Committee (hereinafter referred to as the "CBC"), directed that the majority of fresh frozen plasma be provided by the CRCS to Canadian fractionators. As Canadian fractionators did not

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<sup>13</sup> Ex. 787, Tab 11 (CRCs Position Paper, July 19, 1988).

<sup>14</sup> Ex. 736, Tab 7, p. 103 (CRCs Commentary on the CBC Draft Terms of Reference, April 12, 1982).

<sup>15</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 29707-29712.



have the capacity to process all Canadian source plasma, surplus was sent to commercial fractionators in the United States.

19. As the CBC was not a legal entity, it could not enter into contracts with fractionators. Therefore, the CRCS contracted for fractionation on behalf of the provinces and held a bank account for this purpose. Nonetheless, these fractionation contracts between the CRCS and the fractionators were subject to the approval of the CBC. This will be described in detail in Section B.

20. As discussed in Section B, due, in part, to the financial restraint imposed by its funder, the CRCS did not collect sufficient plasma to produce all of Canada's blood products needs. Consequently, the CRCS was required to purchase blood products from American fractionators which were manufactured from American source plasma. In this respect, the CRCS could not rely upon its own quality control measures, but instead had to rely upon those of the American fractionators and their plasma suppliers. Non-Canadian source plasma was also purchased by Connaught Laboratories Limited (hereinafter referred to as "CLL") who, at times due to its own production problems, wasted the Canadian source plasma delivered to it by the CRCS and had to purchase off-shore plasma from commercial plasma brokers. This practice removed the ability of the CRCS to oversee, in some cases, certain elements of quality control.

#### iv. Distribution

21. The CRCS distributes blood and blood products to hospitals within Canada on a demand basis. The CRCS did not have the option to refuse to supply blood or blood products to hospitals or to dictate its use.<sup>16</sup>

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<sup>16</sup> Evidence of George Weber, Secretary General, National Federation of Red Cross/ Red Crescent Societies, pp. 40497-40498.



22. Blood products were distributed from the seventeen regional blood centres. As noted previously, shortages in one region could be temporarily alleviated by diverting surplus products from another region.

#### v. Clinical Usage

23. The appropriate therapy and the general use of blood and blood products were determined by the physician treating the patient. The CRCS had no power or authority to determine the appropriate treatment of a condition that may require the use of a blood product.

DR. DAVEY: Well, I have said earlier that blood and blood components are very similar. They are biologicals, but in many respects, they are very similar to ethical drugs or drugs which are provided through a physician's prescription. And that essentially means that it is the physician with the patient who makes the decision about what is required for treatment and prescribes it.<sup>17</sup>

This led to some problems as the funders of the blood system wished the CRCS to exert some control over utilization.<sup>18</sup>

#### vi. Policy

24. Within the CRCS, policy formulation for its blood program was described as follows:

DR. HERST: In terms of general policy making, my perception would have been and I think you see very well documented evidence of it in the minutes of the Advisory Committee, there might be a draft policy development by National office staff with input that came out of the Medical Directors' meeting, perhaps with the input from an Ad Hoc Working Group. This would be formulated as a

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<sup>17</sup> *Evidence of Dr. Davey, former Assistant National Director BTS, p. 30009.*

<sup>18</sup> *Evidence of George Weber, Secretary General, National Federal of Red Cross/ Red Crescent Societies, pp. 40497-40498.*



drafted suggested policy that would be brought to the Blood Services or at that time Blood Transfusion Services Advisory Committee.

Depending on the complexity of the issue and depending on whether there was a need for additional input and discussion, that occurred in that forum. If it was a very clear cut issue and the Advisory Committee was satisfied with what had been brought to it, it was endorsed as such.

It may well have been that the discussion -- and I believe there was considerable discussion reflected in these minutes; I was not at that Advisory Committee meeting. What will be brought to the Advisory Committee might be modified by them or might be accepted. Depending on the nature of the policy or procedure that received endorsement or acceptance or modification, it would either, for a formality, be brought forward to the board of the Canadian Red Cross Society for information, and frequently that was done in the periodic report that was presented by the Chair of the Blood Services Advisory Committee at the meeting.

If implementation of this policy had either Society fiscal implications or perhaps Society philosophical implications, it might be discussed and require -- and this is my interpretation of how they were handled -- an additional formal approval at the Society board level.

If it was strictly a scientific decision without fiscal or philosophical implications, my impression was that it would just be presented as part of a report and not require approval for implementation.

MARLYS EDWARDH: It would be presented, though, to the Advisory Committee?

DR. HERST: That always. The Advisory Committee would either present it as a formality in its report or the Chair of the Advisory Committee would bring it for further discussion to the Board of the Society.<sup>19</sup>

25. Outside the confines of the CRCS, policy development was, in part, undertaken by the provincial governments. As funders for the entire blood system and, indeed, the health care system in Canada, the provinces set broad policy objectives for the Canadian blood system. Because the Canadian blood system was national in scope, in order to achieve national blood policies all provincial governments had to form a consensus to formulate the policy. To that end, the Ministers of Health, in cooperation with the Federal Minister of Health and Welfare, formed the CBC. This Committee was comprised of representatives from all of the provincial and federal Ministries of Health. It was the mandated function of this Committee to set policy with respect to the Canadian blood system on behalf of the governments of Canada. While this

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<sup>19</sup> Evidence of Dr. Herst, Medical Director CRC BTS, Toronto Centre, pp. 20431-20434.



Committee lacked legislative basis, the adherence of actors within the blood system to the policies set by the CBC was assured through the CBC control of blood program funds.<sup>20</sup>

#### vii. Regulation

26. The federal government, through the Department of National Health and Welfare, had the authority to regulate the CRCS blood program. Within the Department of National Health and Welfare, the Bureau of Biologics (hereinafter referred to as the "BoB") is responsible for regulating drugs which are listed on Schedule "C" and "D" to the *Food and Drugs Act*.<sup>21</sup>

27. Prior to 1989, the BTS, except for its plasmapheresis process, was not regulated by the BoB.<sup>22</sup> Notwithstanding the desire of the CRCS and the interest expressed by the BoB to regulate CRCS blood collection centres,<sup>23</sup> the federal government did not secure the requisite expertise, nor did it allocate sufficient resources to engage in this activity throughout the 1980's.<sup>24</sup>

28. Blood derivatives and plasma collected by plasmapheresis were included in Schedule "D" to the *Food and Drugs Act* in the 1980's. Consequently, the BoB had regulatory responsibility over these products.<sup>25</sup> This regulation took the form of, *inter alia*, issuance and annual renewal of a license following inspection of a manufacturer by a senior BoB scientist.

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<sup>20</sup> The CBC will be discussed further in section B.

<sup>21</sup> Evidence of Dr. David Pope, Assistant BoB, p. 42491.

<sup>22</sup> Evidence of Dr. David Pope, Assistant BoB, p. 42492.

<sup>23</sup> Ex. 881, Vol. 213, Tab 13, p. 052401-052402 (*Briefing Book on the Canadian Blood System*, April 1991).

<sup>24</sup> Evidence of Dr. Furesz, BoB Panel, pp. 42780-42786.

<sup>25</sup> Ex. 1006, Vol. 252, Tab 5 ("Regulatory Control of Blood Products in Canada" by D.W. Boucher and J. Furesz; and

Ex. 987, Vol. 284, Tab 7 (*Food and Drug Regulations - Division 8 "New Drugs"*).



Generally, manufacturers in Canada were inspected annually. Manufacturers in other parts of North America were inspected every two years.<sup>26</sup> Additionally, manufacturers were required to obtain authorization from the BoB for the sale of each lot of licensed product they sold. The manufacturer was required to submit samples of the finished drug with its test results of the lot in question. These submitted samples were tested in the BoB laboratories in order to confirm the manufacturer's findings.<sup>27</sup>

29. For blood products which were imported from the United States, licenses were required from not only the BoB but also from the U.S. Food and Drug Administration<sup>28</sup> where similar procedural requirements had to be met. The federal regulation of whole blood collections in 1989 gave the CRCS extra clout in seeking extra funds where these funds were necessary to satisfy regulatory requirements.

30. In contrast to Canada, the United States had a highly developed regulatory system. Part of the explanation for the lack of regulatory management was the BoB's belief in the safety of the blood program operated by the CRCS which followed WHO guidelines.<sup>29</sup> The Canadian system was substantially different from the American system because of its all-volunteer donor base. While some blood collectors in the United States permitted financial or other incentives to donors, the CRCS did not.<sup>30</sup> Volunteer donors were considered to be safer, healthier donors than the American donor pool, in part, because there was less IV drug abuse in Canada, a lower

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<sup>26</sup> Ex. 1006, Vol. 252, Tab 5, pp. 040279-040280 ("Regulatory Control of Blood Products in Canada" by D. W. Boucher and J. Furesz).

<sup>27</sup> *Ibid* at p. 040280.

<sup>28</sup> Evidence of Mr. Jack Ryan, former President Cutter Biologicals, p. 38739.

<sup>29</sup> Evidence of Dr. Liston, pp. 43890-43891.

<sup>30</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22726-22727.



endemicity of disease, and a generally healthier population,<sup>31</sup> and, because of the altruistic nature of their actions:

HERST: Perhaps I will start by answering what are the objections to paying a donor. The feeling is in all developed countries that a volunteer donor is a safer donor than a paid donor. Why? Because if someone stands to gain materially from the act of donation, they may not be entirely truthful in the details of the health history or the risk history that they give prior to donation.

Some studies in the past bear that out in terms of monitoring infectious disease markers in two types of population. There is higher incidence of hepatitis markers and sexually transmitted disease markers in a paid donor population.

The volunteer stands nothing to gain. The main reason they volunteer their blood is to do good. They would not knowingly do harm, if they understood the process.<sup>32</sup>

Accordingly, the regulatory system in the United States developed differently than in Canada.

31. Timely regulation of CRCS whole blood collections would have been welcomed as having beneficial effect as it could increase the efficiency of decision-making inherent in operating a national blood program in a provincially-funded health care system. Any operating procedure undertaken by the CRCS which had a funding component required the approval and support of all provinces and territories through the CBC.<sup>33</sup>

32. The BoB recognized a need to regulate as early as 1980.<sup>34</sup> By 1983, the CRCS was developing its own quality assurance programs and asked the BoB to oversee its

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<sup>31</sup> Evidence of Dr. Mathias, former NAC AIDS member, pp. 24629-24630; and

Evidence of Dr. Peter Gill, Director, National Reference Laboratory, pp. 42185-42186.

<sup>32</sup> Evidence of Dr. Herst, Toronto Centre Medical Director, p. 467.

<sup>33</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 30300-30301; and

Evidence of Mr. George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, p. 40477.

<sup>34</sup> Ex. 990, Vol. 236, Tab 20 (Memo from Dr. Furesz to Dr. Liston re: Task Force on Licensed Drugs, dated June 9, 1980).



development.<sup>35</sup> Further to its initial request, in 1984, the CRCS requested in its budget submissions to the CBC that a quality assurance function be established at the National Reference Laboratory. Approval by the CBC in 1985 of this position was coupled with a stern warning that this program was not to be formally developed nor duplicated at a centre level.<sup>36</sup> This limitation placed severe restrictions on the development of a quality assurance program within the CRCS BTS. Although quality assurance at the NRC was important, collection and processing of blood and blood components was undertaken at the centre level.<sup>37</sup> Therefore, the CRCS was discouraged from formalizing quality control at this important juncture.

33. Again, in February 1987, the President of the CRCS, Andrew Fleming, wrote to the Minister of Health, Jake Epp, requesting BoB licensure of its whole blood collection system. Mr. Epp's response was that the CRCS was performing well already and stated that the request would be considered as the Ministry re-evaluated its priorities. In the meantime, the CRCS was to continue along its course of self-regulation.<sup>38</sup>

34. While the CRCS believed that BoB regulation would have assisted in the clarification of the roles of those in the blood system and provided some leadership and direction by a regulatory body, (comparable manner of that of the FDA in the U.S.), the BoB was

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<sup>35</sup> Evidence of Dr. Furesz, pp. 44078-44082; and

Ex. 994, Vol. 240, Tab 48 (August 13, 1983 Memo from Dr. Furesz to Dr. Pope and Dr. Boucher).

<sup>36</sup> Ex. 736, Tab 43, pp. 6-7 (Letter from Dr. D. Leclerc-Chevalier to Mr. G. Weber, February 29, 1985).

<sup>37</sup> Evidence of Dr. Perrault, former National Director BTS, p. 30652; and

Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40771-40772.

<sup>38</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 29960-29962; and

Ex. 739 (Letter from Andrew Fleming to Jake Epp, dated February 23, 1987 and Reply from Jake Epp to Andrew Fleming, dated April 23, 1987).



reluctant to provide a unilateral direction which would affect the provincial funding authorities.<sup>39</sup> Whole blood collection was not regulated by the BoB until 1989.<sup>40</sup>

35. When the blood collection activities of the CRCS were ultimately licensed in 1989, it was welcomed by the CRCS. It did, however, create a new challenge for the CRCS because the governing regulatory regimes were not completely synchronized, which created problems for the CRCS in areas of conflicting rules. For example, both the BoB and FDA have promulgated draft guidelines for the validation of the proposed Computer Information System for Centre Operations (hereinafter referred to as "CISCO"). Although the intent of these draft guidelines are similar, the substance of each and the associated processes are dissimilar. This lack of harmonization has considerably complicated the issue of computer system validation.<sup>41</sup>

### viii. Funding

36. Funding of the Canadian blood system was primarily the responsibility of the provinces. In 1973, the Conference of Health Ministers decided that the CRCS would be 100% funded for its BTS and partly funded for BDR. By 1976, funding for BDR increased to 80%.

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<sup>39</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 29960-29962, 28114-28118; and

Evidence of George Weber, Secretary General, National Federation of Red Cross/Red Crescent Societies, pp. 40772-40773.

<sup>40</sup> Evidence of Dr. Furesz, BoB Panel, pp. 42553-42555, 42773-42775.

*NOTE: In contrast, blood products imported from the United States were subject to two regulatory licensing requirements, those of the BoB and those of the FDA which meant that blood products and test kits imported from the United States faced an additional delay. No attempt was made by the BoB to harmonize its regulatory requirements with the FDA and thus speed up the approval process.*

<sup>41</sup> Ex. 1078, Vol. 268, Part 3, Tab 2, p. 00057 (October 25, 1995 The Canadian Red Cross Society Response to the CISCO Review).



37. From 1982 onwards, the CBC reviewed and approved the CRC BTS and BDR budgets prior to recommending them to the provincial Ministries of Health.<sup>42</sup> Funding of the blood program allowed the CBC to exert a level of control over the management of the blood program. This issue will be discussed more fully in Section B.

2) The American System

38. Since there has been substantial comparison during the Inquiry between the Canadian blood system and that of the United States, it may be helpful to provide an overview of the U.S. system.

39. The United States relied upon a system that was partially volunteer and partially paid. The "volunteer sector" primarily provided fresh blood components for transfusion from non-remunerated blood donors. There were three types of collection facilities: American Red Cross (hereinafter referred to as "AmCross") collection centres, which collected 50% of the nation's blood; community non-profit blood banks, which collected 40% of the nation's blood; and hospital blood banks, which collected 10% of the blood in the United States.<sup>43</sup>

40. Non-Amcross volunteer blood banks often affiliated themselves with one of two voluntary organizations: the Council of Community Blood Banks (hereinafter referred to as "CCBC") or the American Association of Blood Banks (hereinafter referred to as "AABB"). The latter organization set standards and provided accreditation to blood banks which fulfilled its criteria.<sup>44</sup> AABB accreditation allowed a blood bank to participate in the Blood Exchange, a system designed to move blood across state borders from areas of surplus to areas of

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<sup>42</sup> Ex. 736, Tab 7, pp. 19-21 ("Canadian Blood Committee Draft Terms of Reference", *Commentary by the Canadian Red Cross Society*, April 12, 1982).

<sup>43</sup> *Evidence of Dr. Zuck, former Director of Blood and Blood Products, FDA*, pp. 22278-22280.

<sup>44</sup> *Evidence of Dr. Francis, Epidemiologist*, pp. 21514-21517.



shortage<sup>46</sup> according to the demands of the market.<sup>46</sup> AmCross had a similar distribution centre to which surplus blood products and components were sent for exchange with other Amcross Centres.<sup>47</sup>

41. Unlike Canada, there was no single agency responsible for the collection of whole blood. Even in the volunteer sector, blood was a commodity which was bought and sold on the commercial market by way of the AABB or AmCross blood exchanges, long term contracts of supply or spot market purchases<sup>48</sup>:

ZUCK: You know, I think we spoke Tuesday of three different modes in which it moves. It moves through the Red Cross hub system, which is half of what moves. Well, I know half of what is drawn moves through that. The second mode is by long and short-terms contracts, which may or may not go through the clearing house or so-called "Exchange" or the American Association of Blood Banks. And the third method is spot markets, and I didn't like to, but much like pork bellies. People don't like that analogy with blood. There is something unpleasant about relating it to pork bellies. But the market works the same way. Although, I don't know of any futures in blood.<sup>49</sup>

42. Although most regions of the United States were serviced by one blood bank and perhaps a small hospital which also collected blood, there were "turf wars" in some areas and competition for donors. Shopping for discounts in blood based on volume was common.<sup>50</sup> There was even competition between the commercial and volunteer sectors.<sup>51</sup>

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<sup>46</sup> Evidence of Dr. Zuck, former Director of Blood and Blood Products, FDA, pp. 22289-22291.

<sup>47</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22321-22322.

<sup>48</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22319-22325.

<sup>49</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22322-22323.

<sup>50</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22708.

<sup>51</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22715-22716.

<sup>51</sup> Evidence of George Weber, Secretary General, National Federation of Red Cross/Red Crescent Societies, pp. 40409-40410.



43. For decades American blood banks operated within a well-developed regulatory framework, which evolved as a result of the commercial plasma sector. A licensing and inspection process to ensure the safety of blood and plasma was established by The Food and Drug Administration (hereinafter referred to as "FDA"), a division of the United States Public Health Agency, the Department of Health and Human Services (hereinafter referred to as "HHS"). This body had far-reaching powers to close down a fractionation facility or a blood bank for failure to comply with its standards.

44. The highly structured regulatory environment, which was enacted because of the paid plasmapheresis industry, affected the standards of the volunteer sector as well. Even prior to 1983, some American volunteer blood banks were using certain donor screening measures, such as conducting physical examinations of donors, taking blood pressure and temperature, using a tick-the-box health questionnaire<sup>52</sup>, a donor screening pamphlet, and providing privacy areas in which to fill out the questionnaire. Many blood donor clinics were mobile clinics run out of specially fitted and designed vehicles which contained all the necessary equipment to run a blood donor clinic, including privacy areas.<sup>53</sup> Such donor screening requirements were already standard in the system in which the volunteer sector and the commercial plasma sector operated in parallel.

45. Donors responding to enticements have more motivation to be less than candid with the blood collector. It was believed that altruistic donors had no incentive to lie.<sup>54</sup> The

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<sup>52</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 27685-27686;*

*Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22400; and*

*Evidence of Dr. Herst, Toronto Centre Medical Director, p. 20321.*

<sup>53</sup> *Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22383-22384.*

<sup>54</sup> *Evidence of Dr. Macpherson, former Medical Director of Health, City of Toronto, pp. 3478-3480;*

*Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22407-22408; and*

*Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 465-467.*



incentive received by paid donors compensated them for any embarrassment or inconvenience they might have suffered from donor screening. A paid donor could always be subjected to more intrusive donor screening measures so long as the incentive was adequate.<sup>55</sup> Non-volunteer blood banks need not worry about alienating donors and thereby threatening levels of collections. In the United States, a "paid" donor received money for his or her donation. However, volunteer donors might also receive small gifts, such as T-shirts, for donating blood. It was not known how valuable such a gift must be before it provided an incentive for a donor to give a false health history.

MR. HARVEY: How does the FDA define "paid"?

DR. ZUCK: With great difficulty, and it has generally been -- it has generally been left up to the discretion of inspectors about whether something is paid. Dollars are clear. The most common definition, and it has more or less been accepted by the Food and Drug Administration, is any form of remuneration that is readily convertible to cash.

Now, not everyone accepts that, but that is kind of a working definition. So then you get involved -- what do you do with T-shirts that they give away and this kind of thing for donor incentives?

And we are not sure of what donor incentive, what it really does to the health history honesty...

But we have detailed questions about incentives to try to get our arms around what makes a person not have a truthful answer. Is it a T-shirt, theatre tickets, something -- is readily convertible cash a good thing? The one thing that the agency has declared itself on is credit plans, that if you donate blood, and your family is put on a blood assurance program, that you get a discount if you need blood in the future, because you can't sell those, their not readily convertible cash. Those have not been considered a paid donor, but some people would view it as paid.<sup>56</sup>

46. Blood shortages could be overcome by providing greater incentives to healthy donors. Moreover, any increased costs associated with stepping up blood donor recruitment to compensate for higher donor deferral rates, or implementing new donor screening measures

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<sup>55</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22857-22859, 22398-22399.

<sup>56</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22726-22728.



could be passed on to the ultimate consumer under the American system, which operated on a cost recovery basis as the blood bank charges the hospital for the supply of blood. In 1980, the average cost to a community blood centre for the collection of one unit of whole blood was \$46.00.<sup>57</sup> This cost was passed on to the patient, along with an administration charge for such services as cross-matching, as part of the patient's hospital bill. This applied even where the cost increase was significant, such as in the case of a new blood test.<sup>58</sup>

47. This procedure was standard for every blood bank. As the cost was approximately the same for all, the consumer had no choice but to pay. Because of the cost recovery system, American blood banks did not have to overcome many of the delays and hurdles faced by the CRCS and outlined below in dealing with its central funding authority. In summary, the American blood system balanced its inherently more dangerous donor pool with a more regulated recruitment, screening and collection process.

### 3) Summary

48. Throughout the 1980's, the CRCS operated within a system of divided control and uncertain responsibilities in the absence of contractual or statutory direction or a national blood policy. The unregulated blood system<sup>59</sup>, with no national policy, overseen by the CBC whose primary interest was funding,<sup>60</sup> was incapable of providing leadership in responding to AIDS. While CRCS was not the only actor in the system whose appropriate role was to respond to AIDS (as will be discussed in the following sections) it often undertook more than was within its sphere of responsibility. As Dr. Perrault testified before the Inquiry:

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<sup>57</sup> Ex. 746, Tab 6 (OTA Report, *Blood Policy & Technology, Part I*, p. 157).

<sup>58</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22323-22324.

<sup>59</sup> Except for blood products as described herein

<sup>60</sup> See Section B - Canadian Blood Committee herein.



PERRAULT:...We were part of a system...we were not operating alone,...I am getting the impression that we were the only people in this country dealing with AIDS, and that is not so".<sup>61</sup>

49. The CRCs attempted to overcome the leadership void by taking the initiative to get parties together to discuss important issues surrounding AIDS. Examples will be more fully outlined in the next sections.

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<sup>61</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 29752.*



B.

## CANADIAN BLOOD COMMITTEE

### 1) Formation of the CBC

#### a) The FPPBRC

50. Prior to the formation of the CBC in 1982, the CRCS Blood Program budget was reviewed and approved by the Federal/Provincial Program and Budget Review Committee (hereinafter referred to as "FPPBRC"). The mandate of this Committee was authorized by the 1973 conference of Deputy Ministers of Health and was reaffirmed, under a modified organizational structure, at the October 1980 meeting of the Federal/Provincial Advisory Committee on Institutional and Medical Services. The FPPBRC's mandate read as follows:

In recognition of the principle that this service constitutes a national program, the federal government, with regional advice and in consultation with provincial health insurance authorities, shall have authority to evaluate the budgets and programs of the Blood Transfusion and Donor Recruitment Services of the Canadian Red Cross Society.

The federal government, in conjunction with at least one provincial representative, shall approve the final budget annually and advise the provinces of the total cost of the programs, the approved new programs and the respected provincial allocation of costs on an agreed basis of allocation.<sup>61</sup>

51. At the request of the Ad Hoc Committee of Deputy Ministers of Health on Blood and Blood Products in 1980, this Committee was also asked to monitor contracts between the CRCS and fractionators<sup>62</sup> following a controversy in that year outlined below wherein the CRCS

<sup>61</sup> Ex. 872, Vol. 204, Tab p. 51 (Document entitled, "Management of the Canadian Blood Program", February, 1981).

<sup>62</sup> Ibid, p. 52.



awarded its fractionation contract based on its own selection criteria rather than provincial priorities.<sup>63</sup>

52. The FPPBRC was comprised of two federal and three provincial officials. Provincial representation was provided on a regional basis: one western, one central, and one eastern representative. Quebec withdrew from this Committee in 1980 and dealt separately with CRCS until it joined the CBC in 1984.<sup>64</sup>

b) **Fractionation Debate - The Provinces Get Interested**

53. The concept of a body to oversee the blood system to ensure provincial priorities were achieved, emerged following the studies on the future of plasma fractionation in Canada. These studies, conducted by senior federal and provincial health officials, included the Ad-Hoc Committee on Plasma Fractionation (1977), the Ad Hoc Committee on Blood and Blood Products (1979) and the 1980 Inter-Provincial Committee on Plasma Fractionation.

54. In May 1977, the Deputy Ministers of Health established a Federal/Provincial Ad Hoc Committee on Plasma Fractionation to examine the issue of plasma fractionation in Canada and to make recommendations to the conference of Deputy Ministers on how Canada's future blood product requirements should be met.<sup>65</sup> The Committee completed its report in February 1979 and recommended the establishment of a "management board" for the blood system comprised of CRCS and government representatives.<sup>66</sup> It was also recommended that a 200,000-litre fractionation plant, owned and operated by the CRCS under the supervision of the

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<sup>63</sup> See paragraphs 10 - 12, *infra*.

<sup>64</sup> *Ex. 859, Vol. 191, Tab 3, p. 125 (Record of Decisions of the CBC, October 25, 1984).*

<sup>65</sup> *Ex. 870, Vol. 202, Tab 15 pp. 135-136 (Report of the Federal/Provincial Ad Hoc Committee on Plasma Fractionation, p. 103).*

<sup>66</sup> *Ibid, p. 113.*



proposed management board, be established to ensure the effective organization of the National Blood Services and the principals enunciated by the Ministers of Health.<sup>67</sup>

55. This report was presented to the Federal/Provincial Conference of Deputy Ministers of Health on March 6 and 7, 1979. The governments of Ontario, Quebec and Manitoba opposed the conclusions in the report.<sup>68</sup> These provinces wished to build or support the fractionation plants in their own provinces. Adopting the report would curtail their goal of their own provincial fractionation facility.

56. The Deputy Ministers decided not to set up a management board nor direct the CRCs to construct a plasma fractionation plant. Rather, they determined that these matters should be decided after the formulation of a Canadian blood policy and directed that an Ad Hoc Committee on Blood and Blood Products, chaired by Mr. G.J. Chatfield of Alberta, be constituted to formulate such a policy.<sup>69</sup>

57. The Chatfield Committee reported to the Federal/Provincial Conference of Health Ministers in September 1979. While no Canadian blood policy was formulated,<sup>70</sup> the Committee made the following recommendation with respect to the management of the blood system:

In order to facilitate the implementation of the decisions made concerning the principles, issues and options which have been presented by the sub-committee of Deputy Ministers on blood and blood products, the Committee recommends

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<sup>67</sup> *Ibid*, p. 117.

<sup>68</sup> Ex. 870, Vol. 202, Tab 17 pp. 135-160 (*Minutes of Meeting of the Conference of Deputy Ministers of Health, March 6 and 7, 1979*); and

Ex. 870, Vol. 202, Tab 13 (*Letter from Mr. F.S. Anderson, Director, Administration Division, Manitoba Health Services to Dr. H.W. Jackman, Chairman, Ad Hoc Committee on Plasma Fractionation, January 24, 1979*).

<sup>69</sup> Ex. 870, Vol. 202, Tab 17, p. 136 (*Minutes of the Conference of Deputy Ministers of Health, March 6 and 7, 1979*).

<sup>70</sup> Ex. 870, Vol. 202, Tab 24, p. 198 (*Report Submitted to the Federal/Provincial Conference of Health Ministers, September, 1979 by the Ad Hoc Committee on blood and blood products*).



that an ad hoc federal-provincial committee of Deputy Health Ministers be established. The ad hoc committee will be chaired by a provincial representative, and will consist of one representative from the federal government and one representative from each province signifying its wish to participate.<sup>71</sup>

58. The Chatfield Committee also recommended that only non-profit operations be permitted within the processing component of the Canadian blood system. It proposed that the Federal government review and change the corporate status of CLL and its present profit-oriented objectives so CLL would not be excluded from consideration as a fractionator of Canadian blood.<sup>72</sup> CLL, a profit-oriented pharmaceutical company, was Ontario's candidate to be the primary fractionator of CRCS plasma. The Committee also recommended a one-year contract between CLL and the CRCS. Under the recommendation, CLL would continue to receive and fractionate CRCS stored plasma and outdated blood. CLL would also receive and fractionate CRCS fresh frozen plasma at a level sufficient to allow CLL's total plasma fractionation to reach the 90,000-litre level. This recommendation was made to ensure CLL's survival until the fractionation issue was resolved.<sup>73</sup> The CRCS plan for an integrated system, meanwhile, remained in limbo.

59. In 1980, the CRCS put out tenders for contracts to fractionate CRCS fresh frozen plasma. Among others, CLL and Cutter Laboratories responded to this Request for Proposal (hereinafter referred to as "RFP"). On May 8, 1980, Dr. Perrault wrote to Mr. Don McNaught, the Chair of the Federal/Provincial Budget Review Committee, stating that in view of the quality of service offered and the minimum saving of \$4.5 million (32%) over the next best bid submitted, the CRCS wished to sign the contract with Cutter.<sup>74</sup> On June 6, 1980 the CRCS received a telex from Mr. McNaught advising it (on behalf of Mr. Chatfield of the Ad-Hoc Committee of Deputy Ministers on Blood and Blood Products) that the consensus of provinces

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<sup>71</sup> *Ibid*, p. 220.

<sup>72</sup> *Ibid*, p. 214.

<sup>73</sup> *Ibid*, pp. 218-219.

<sup>74</sup> Ex. 610, CRC Vol. 7, Tab 39 (*Letter from Dr. Roger Perrault to Mr. D. McNaught, May 8, 1980*).



was to accept the tender of Cutter Laboratories.<sup>75</sup> Based on the authorization of the Chatfield Committee, the CRCS accepted the Cutter contract.

60. • In August 1980, Mr. Alan Dyer of the Ontario Ministry of Health, asked the CRCS to forward a copy of the finalized contract with Cutter. The CRCS complied with this request. On September 5, 1980, the Assistant Deputy Ministers of Health and Industry and Tourism of Ontario instructed the CRCS to cancel the Cutter contract at the earliest possible date and re-direct all plasma under the Cutter contract to CLL.<sup>76</sup> The CRCS noted Ontario's strong feelings and suggested that this matter be taken up at the October 1980 Conference of Inter-Provincial Ministers of Health. The Cutter contract issue was not resolved at the Conference. Subsequently, Ontario forced the CRCS to cancel this contract.<sup>77</sup>

61. Ontario's unilateral act highlighted the problem of having the national blood program funded by the individual provinces. It reiterated the need to establish clear roles and responsibilities within the system.

c) **The Chapin Key Committee**

62. At the October 1980 Conference of Inter-Provincial Ministers of Health, the Inter-Provincial Ad Hoc Committee on Plasma Fractionators (hereinafter referred to as the "Chapin Key Committee") was formulated. It was delegated the role of evaluating the feasibility of producing blood products by one or more of the three plants operated by CLL (Ontario), Rh Institute (Manitoba) and Armand-Frappier (Quebec). The possibility of a fractionation plant

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<sup>75</sup> Ex. 610, CRC Vol. 7, Tab 41 (Telex from Mr. D.C. McNaught to Dr. Roger Perrault, June 6, 1980).

<sup>76</sup> Ex. 611, CRC Vol. 8, Tab 16, p. 85908 (Memo from National Co-ordinator, Public Relations, to National Executive Committee Members, September 12, 1980).

<sup>77</sup> See Section II.C, *infra*.



owned and operated by the CRCS was specifically excluded from consideration as no province was willing to champion the cause of an integrated blood system.<sup>78</sup>

63. Six weeks later, the Chapin Key Committee completed its report. It noted that there was no Canadian body similar to the Bureau of Blood Products in the United States to oversee the collection, processing and supply of blood products, including the export and import of these products.<sup>79</sup> The Committee further noted the uncertainty created in the absence of such an authority to develop a policy concerning blood resources and facilitate consensus among the groups concerned with the supply and utilization of these resources.

64. The Chapin Key report confirmed the observations of earlier committees and recommended the development of a Canadian authority to oversee the blood program, develop principles, resolve other issues raised,<sup>80</sup> as well as, if necessary, to control and monitor the blood collection, processing and distribution.<sup>81</sup> Attached to the report were draft terms of reference for a Canadian blood authority.<sup>82</sup>

65. In December 1980, the provincial Ministers of Health accepted the recommendation to develop an overseeing body. Accordingly, the Chapin Key Committee was asked by the Ministers to further develop this recommendation.<sup>83</sup>

66. At this meeting a number of Health Ministers voiced their disapproval of the public questioning by the CRCS of the Ministers' October decision to exclude a CRCS

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<sup>78</sup> Ex. 871, Vol. 203, Tab 9, p. 91 (*Inter Provincial Conference of Health Ministers, September 30 and October 1, 1980, Chairman's Statement of Disposition of Agenda Items*).

<sup>79</sup> Ex. 871, Vol. 203, Tab 10, p. 115 (*Report to the Provincial Ministers of Health, November 1980 by the 1980 Inter Provincial Ad Hoc Committee on Plasma Fractionation*).

<sup>80</sup> *Ibid*, p. 162.

<sup>81</sup> *Ibid*, p. 115.

<sup>82</sup> *Ibid*, p. 164.

<sup>83</sup> Ex. 872, Vol. 204, Tab 17, pp. 141-142 (*Report to the Provincial Ministers of Health, September, 1981 by the 1981 Inter-provincial Ad Hoc Committee on a Canadian authority on blood policy*).



fractionation plant from consideration. The CRCS took the position that, as collectors and distributors of blood and plasma in Canada, it should exert some control over who fractionated the blood products. Mr. Timbrell indicated that he would retaliate with an audit of the CRCS:

...They [CRCS] are being subsidized at a very high rate, thank you very much, by the governments of the ten provinces to provide this service for the health care system. It's not their blood. The blood belongs to the people of the provinces and for them to adopt this kind of an attitude as displayed in this missile, which I say I presume went to all provinces, as apparently displayed at some of the meetings with various ministers and certainly displayed at some of the public pronouncements, disturbs me very, very much. I know one of the things that I am going to follow-up in this province; we have a new Provincial Audit Act in which the Provincial Auditor has the right, indeed the mandate, to go into any organization which is being funded by the provincial government and to comment about the organization on the basis of whether we are getting value for money expended. I am going to make damn sure that the Red Cross is one of the first things audited.<sup>84</sup> (Emphasis original)

67. The Chapin Key Committee reported again in September 1981. It concluded that a single authority, with input from the various sectors, was necessary to provide a focus for working towards consensus, arriving at policies and giving direction. Because the Canadian blood system functioned nationwide, all provincial governments were to have representation. In addition, as the system had to respond to change, the authority required an organizational mechanism to allow expression and input from various interest groups. It was to remain independent from any particular group.<sup>85</sup>

68. The Chapin Key Committee further noted that:

The emotional overtones to "blood" ensures that many of these issues will be morally, ethically and politically sensitive. In order to resolve such matters in a comprehensive, fair manner there needs to be an authority that is viewed as impartial but which has a mandate to address these sorts of issues. The Health

<sup>84</sup> Ex. 871, Vol. 203, Tab 12, p.230 (*Transcript: Inter-provincial Conference of Ministers of Health, December 15-16, 1980*).

<sup>85</sup> Ex. 872, Vol. 204, Tab 17, p. 141 (*Report on the Provincial Ministers of Health, September, 1981 by the 1981 Inter-provincial Ad Hoc Committee on a Canadian authority on blood policy*).



Ministers will be better able to deal with these moral, ethical and politically sensitive issues because of the forum created by such an authority.<sup>86</sup>

69. The Canadian Authority on Blood Policy (hereinafter referred to as "CABP"), as proposed by the Chapin Key Committee, would be incorporated under federal law with legal and financial authority to contract for services and products. The CABP was to enter into an agreement with the CRCS, whereby the CRCS would collect, process and distribute blood and blood products, and negotiate plasma fractionation contracts. The CRCS would submit budgets for BDR, BTS, and other services or products, for review and approval by The CABP.<sup>87</sup> Most importantly for the provinces, the CABP was to approve the CRCS budget and allocate costs to the provinces and territories.<sup>88</sup>

70. The CABP was to direct the CRCS on which fractionation plants were to be considered for processing blood plasma collected from volunteer donors and determine the amount of plasma to be allocated to each plant. While day-to-day operations of BDR and BTS would remain with CRCS, questions of policy and blood program approval would rest with the CABP. The CABP would act as a consultant to the Department of Industry, Trade and Commerce on the import and export of human blood and blood products and consult with the BoB on the inspection and licensing of plasmapheresis and plasma fractionation centres.<sup>89</sup>

71. The final report containing the above recommendations of the Chapin Key Committee was presented to the Conference of Provincial Health Ministers held on September 30, 1981. Ontario, Quebec, and Manitoba were opposed to such an authority. According to Mr. Timbrell, the Ontario Minister:

...It seems to me that, certainly, a lot is to be said for an ongoing inter provincial advisory body, but, as far as this key issue is concerned, I just can't

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<sup>86</sup> *Ibid*, p. 142.

<sup>87</sup> *Ibid*, p. 153.

<sup>88</sup> *Ibid*, pp. 153-154.

<sup>89</sup> *Ibid*, pp. 154-155.



see that my Government could turn that over and lose any direct control of what happens in our Province.<sup>90</sup>

72. Ultimately, the Provincial Ministers of Health agreed upon the CBC, a federal/provincial committee with representation from each province. Representation on the CBC was to consist of senior civil servants. It would not have formal delegated authority. The Ministers left the technicalities of running the CBC to their appointed officials to determine.<sup>91</sup> The provincial Ministers of Health gave the CBC the same terms of reference as the proposed Canadian authority on blood policy, with the exception that it was to recommend the blood program budget to the provincial Health Ministers, rather than approve it.<sup>92</sup>

## 2) CBC Terms of Reference

73. During the course of the Chapin Key Committee deliberations, the CRCS offered assistance but had no formal input into this new structure.<sup>93</sup> The final terms of reference of the CBC read as follows:

### Purpose

To direct the Canadian blood system in accordance with the principles established by the Ministers of Health for the therapeutic use of human blood, blood products or their substitutes.

### Objectives

1. To establish policies with regard to the following:

- a) the collection of blood, including plasmapheresis;
- b) the processing of blood;

<sup>90</sup> Ex. 873, Vol. 205, Tab 10, p. 62 (*Excerpt of Transcript of Conference of Provincial Health Ministers, September 30-October 1, 1981, St. John's Newfoundland*).

<sup>91</sup> *Ibid*, pp. 121-123.

<sup>92</sup> Ex. 858, Vol. 190, Tab 3, p. 8 (*Draft Record of Decisions of the Canadian Blood Committee, February 3-4, 1982*).

<sup>93</sup> *Evidence of Dr. Perrault, former National Director BTS*, p. 30605.



- c) the distribution of blood products;
- d) the utilization of blood products;
- e) operational research; and
- f) support and maintenance of the four enunciated principles concerning blood and blood products.

2. To recommend allocation of resources to meet costs of implementing the above policies.
3. To assure adherence to established policies by the Canadian Red Cross, plasma fractionation plants, and others involved in the collection, processing, distribution and utilization of blood and blood products.
4. To consult with the Department of Industry, Trade and Commerce on appropriate policies for the export and import of human blood and blood products.
5. To consult with the Bureau of Biologics, Department of National Health and Welfare, on appropriate policies for the regulatory control of the collection, processing, and distribution of blood, blood products and their substitutes.
6. In the short term, to monitor the development of fractionation plants to ensure that their establishment is in accordance with the recommendations of Ministers of Health and allocate resources and priorities for their implementation.
7. To determine the real costs of producing blood fractions for Canadians and the shareable portion of capital costs to be added to the price of blood fractions.
8. To ensure that standards for blood, blood products and blood substitutes are developed, and to monitor that such standards are met.
9. To review and approve the programs and budgets of the Blood Donor Recruitment and Blood Transfusion Services of the Canadian Red Cross Society, subject to the concurrence of all Provinces and Territories.
10. To report annually to the Ministers of Health on all activities of the Committee.
11. To be a national forum for the various organizations and associations of the Canadian blood program to discuss issues, and to coordinate the activities related to the management of the Canadian blood system.

APPROVED

February 3, 1982<sup>94</sup>

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<sup>94</sup> Ex. 858, Vol. 190, Tab 3, pp. 17-18 (*Draft Record of Decisions of the Canadian Blood Committee, February 3-4, 1982*).



74. The CBC met for the first time in December 1981. At this meeting, Dr. Roger Perrault was presented with the CBC terms of reference as a draft and was asked to comment.<sup>95</sup> As requested, the CRCS formulated a thorough commentary on the terms of reference of the CBC by April of 1982.<sup>96</sup> Unbeknown to the CRCS, the draft terms of reference had already been approved on February 3, 1982 without notifying the CRCS or waiting for its commentary.<sup>97</sup>

75. The overall purpose of the CBC as stated in its terms of reference was "to direct" the Canadian blood system in accordance with the principles established by the Ministers of Health for the therapeutic use of human blood, blood products and their substitutes. The CRCS was concerned that the term "to direct" and the authority and accountability of the CBC was not delineated or defined. It was also unclear how much day-to-day involvement the CBC was to have with the management of the blood program. The CRCS noted in its commentary that government funding of the Canadian blood program was now evolving into government direction and control without a legislative basis and identified public accountability.<sup>98</sup>

76. The CRCS pointed out that various international resolutions acknowledged the need for national government regulation of transfusion services.<sup>99</sup> There was no indication in the CBC terms of reference of any intent to support regulation of the blood program by the federal government. The CRCS expressed concern that management decisions may be made by the CBC without legislative basis and without legislative consequence. Further, such decisions might be made on the basis of political and economic imperatives. In particular, the CRCS was

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<sup>95</sup> Ex. 858, Vol. 190, Tab 2, p. 7 (*Record of Decisions of the Executive Committee of the CBC, December 3, 1981*).

<sup>96</sup> Ex. 736, Tab 7 (*Commentary by the Canadian Red Cross Society on Canadian Blood Committee Draft Terms of Reference, April 12, 1982*).

<sup>97</sup> Ex. 858, Vol. 190, Tab 3, p. 8 (*Draft Record of Decisions of the Canadian Blood Committee, February 3-4, 1982*).

<sup>98</sup> Ex. 736, Tab 7, p. 29 (*Canadian Blood Committee draft Terms of Reference Commentary by the Canadian Red Cross Society*).

<sup>99</sup> *Ibid.*, p. 30.



concerned that contracts with fractionators would no longer be awarded on a best-proposal basis but on the basis of political/economic apportionment.<sup>100</sup>

77. The decision of the Ministers of Health to move to a Canadian multi-plant solution for fractionation was a serious concern for the CRCS. Previously, the CRCS had been in a position to select the best fractionator available to process Canadian plasma. The CBC terms of reference appeared to give the CBC the authority to determine how much plasma was allotted to each Canadian fractionator. Thus, the CRCS lost an important element of its quality control. The non-profit principle and the fact that the Canadian fractionators received a guaranteed amount of plasma meant that the competitive element of fractionation was removed. Accordingly, the three Canadian fractionators might have less incentive to improve the quality of their product which could have a deleterious effect on the quality of blood products provided to Canadians.<sup>101</sup>

78. Finally, the CRCS raised the concern that as budgets would no longer be reviewed by the federal Ministry of Health and Welfare in conjunction with provincial representatives, the public accountability of the authorities making policy and budgetary decisions may suffer. The CRCS felt strongly that public accountability of the CBC had to be established.<sup>102</sup>

79. The CBC did not view the concerns of the CRCS in a favourable light. Mr. Stephen Dreezer, the Ontario representative, referred to the CRCS report as a "pile of crap".<sup>103</sup> The CBC saw no need to change the terms of reference.<sup>104</sup> The CBC appeared to be embarrassed by the fact that, notwithstanding the fact that the CRCS was asked to comment on these terms of reference, they had already been approved. The CBC agreed that in the event

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<sup>100</sup> *Ibid*, p. 30.

<sup>101</sup> *Ibid*, pp. 35-36.

<sup>102</sup> *Ibid*, p. 37.

<sup>103</sup> Ex. 736, Tab 8 (*Handwritten notes of Dr. Perrault, former National Director, BTS*).

<sup>104</sup> Ex. 858, Vol. 190, Tab 9, p. 187 (*Approved Record of Decisions of the Canadian Blood Committee, August 26, 1982*).



the CRCS raised this issue they would inform it that the terms of reference had been approved subject to the comments of the CRCS.<sup>105</sup>

80. During the August, 1982 meeting, the CBC was dismissive of the concerns of the CRCS. The CBC members informed the CRCS that the commentary revealed "no significant difference of opinion"<sup>106</sup> between the goals set out in the terms of reference and the position of the CRCS. Nevertheless, the CBC reassured the CRCS that the terms of reference were not "fixed in stone" and could change at any time.<sup>107</sup> During the Inquiry, however, Mr. Hearn testified that the CBC could not change its own terms of reference.<sup>108</sup> At no time did the CBC seek to modify its terms of reference.<sup>109</sup>

### 3) Structure of the CBC

81. From 1981 to 1991, the CBC was the vehicle that directed the Canadian blood system, which encompassed elements of collection, processing, distribution and funding of blood and blood products. The CBC was not envisioned to be a management vehicle.<sup>110</sup> Direction of the blood system by the CBC was to have been in the form of policy development so as to provide a framework for the CRCS to fulfil its function as the operator of the blood program and distributor of blood products:

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<sup>105</sup> Ex. 858, Vol. 190, Tab 8, pp. 171-172 (*Meeting Report Canadian Blood Committee/Canadian Red Cross Society Senior Officials, August 26, 1982*).

<sup>106</sup> Ex. 858, Vol. 190, Tab 8, p. 172 (*Meeting Report Canadian Blood Committee/Canadian Red Cross Society Senior Officials, August 26, 1982*).

<sup>107</sup> Ex. 858, Vol. 190, Tab 8, p. 172 (*Meeting Report Canadian Blood Committee/Canadian Red Cross Society Senior Officials, August 26, 1982*).

<sup>108</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, pp. 35429-35430.*

<sup>109</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, p. 35439.*

<sup>110</sup> Ex. 737, Tab 23, p.2 (*The Management of Canadian Blood System - A Discussion Paper of the Ad Hoc Working Group, August 25, 1989*).



HEARN:...The (Chapin Key) committee conceived of this authority as, if you will, a body that would on behalf of governments, do what governments do; set broad policy guidelines, allocate funding. But it never conceived of itself as operating the system, of managing it on a day-to-day basis, of getting its hands involved in it.

It conceived of it as an authority to respond to the policy, the broad policy questions and the funding issues.<sup>111</sup>

82. However, its role as a funder entailed a significant level of interference with the day-to-day operation of the CRCS blood program.<sup>112</sup>

a) **Authority and Composition of the CBC**

83. The CBC was comprised of 13 representatives. Each province and territory and the federal government was entitled to a seat on the CBC. In practice, the territories seldom sent a representative.<sup>113</sup> The CBC had no officially delegated authority from the provincial or federal health ministries which presented a problem with respect to approval of expenditures and funds in the CRCS blood program. While some individual provincial representatives were given authority to approve the CRCS blood program budget, others required prior approval by their provincial treasury boards.<sup>114</sup>

84. The CBC had one source of funds under its control, the fractionation account, which was held on its behalf by the CRCS. It was intended to be the source for payment of blood products. The CBC did not appear to require prior treasury board approval to use funds in the fractionation account.

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<sup>111</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, p.35311.*

<sup>112</sup> *Ex. 737, Tab 23 (Final Report of the Ad Hoc Working Group, August 25, 1989).*

<sup>113</sup> *Ex. 862, Vol. 194, Tab 6, (Draft Record of Decisions of the CBC, June 26 to 27, 1986. Although Yukon and Northwest Territories are listed as members of the Canadian Blood Committee, it does not appear that Yukon ever sent a representative to the CBC. Northwest Territories apparently had a representative attend on the June 23 to 24, 1986 meeting, but not attend regularly apart from this.).*

<sup>114</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, pp. 35425-35427.*



85. The CBC used the fractionation account as its own contingency fund.<sup>115</sup> This was evidenced by the fact that no request was made to the various ministries of health to authorize the payment of up to \$150,000 per month to CLL as a form of temporary relief in 1985 while that fractionator attempted to develop a heat-treatment process:

While the Red Cross assumed that the handling of the financial assistance regarding indirect costs involved additional payments by the provinces and territories, the members (of the CBC) disagreed. It was proposed that all approved assistance be charged to the fractionation account (the accumulated revenues therein). There shall be no revision to the pricing of fractions approved for 1985. Simply stated, the up to \$900,000 (i.e. up to \$150,000 times up to six months) in assistance will come out of the Society's accumulated fractionation revenues which are, in effect, monies held in trust for the CBC. It was acknowledged that with this money gone, the Society would incur higher financing costs pertaining to fractions inventory and receivables. The proposal was accepted by all.<sup>116</sup> (Emphasis original)

86. Although members of the CBC came from their respective health ministries, they were not all at the same level of the political hierarchy. For example, the Newfoundland representative was a Deputy Minister of Health. The Ontario representative was two levels below that, and the Quebec representative was at a lower level yet.<sup>117</sup>

87. Although a few medical doctors served on the CBC, none had specific technical or scientific instruction in blood matters. The majority of CBC members had accounting backgrounds.<sup>118</sup> Dr. Leclerc-Chevalier, the Executive Director of the CBC, observed in 1984 that a significant lack of knowledge was exhibited by various provincial representatives concerning the blood program.<sup>119</sup>

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<sup>115</sup> *Evidence of Mr. Claude Morin, former National Administrator, CRC BTS, pp. 39857-39858; and Evidence of Mr. Randall Klotz, CBC Panel, p. 36863.*

<sup>116</sup> *Ex. 860, Vol. 192, Tab 10, p. 244 (Record of Decisions of the Canadian Blood Committee, April 17, 1985).*

<sup>117</sup> *Evidence of Mr. Stephen Dreezer, former Member of the CBC Panel, p. 35435.*

<sup>118</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 30601.*

<sup>119</sup> *Ex. 736, Tab 36 (Memorandum from Dr. Perrault to Mr. G. Weber, June 12, 1984).*



88. In addition to their roles as members of the CBC, these individuals had other duties. Membership on the CBC was never a representative's primary duty within his or her Ministry of Health.<sup>120</sup> Meetings were held infrequently and were seldom attended by the full complement of CBC members.<sup>121</sup> In 1984 for example, at least one provincial member and, on one occasion, the federal representative was absent from each meeting.<sup>122</sup> The CRCS attended only by invitation for specific issues.

89. Appointees to the CBC were changed on a regular basis. New members frequently required education to address issues in the blood program.<sup>123</sup> Most members, accustomed to hospital budgets, expected the format of the CRCS budget to be no different.<sup>124</sup> This was an unrealistic expectation, as the operations of a national blood program in ten provinces with multiple components was quite unlike that of a hospital.

90. The CBC was serviced by a secretariat of four. This included an executive director, a program analyst, a financial analyst, and a secretary. The secretariat's primary responsibility was in reviewing and making recommendations on the blood program budget prepared by the CRCS to the CBC.<sup>125</sup> In addition, the secretariat informed the members of the

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<sup>120</sup> Evidence of Mr. Stephen Dreezer, former member of the CBC Panel, p. 35285.

For example, Mr. Stephen Dreezer was the Executive Director of the Institutional Health Division in the Ministry of Health for Ontario with responsibilities for maintaining and operating the capital budgets for Ontario hospitals.

<sup>121</sup> Exs. 859-862, Vols. 191-194 (Minutes of Meetings of the Canadian Blood Committee 1984-1985).

For example, in the years 1984 and 1985 there were only three meetings of the full Canadian Blood Committee in each year.

<sup>122</sup> Exs. 859-861, Vols. 191-193 (Minutes of Meetings of the Canadian Blood Committee).

<sup>123</sup> Evidence of Dr. Perrault, former National Director BTS, p. 30602.

<sup>124</sup> Ex. 862, Vol. 194, Tab 4, p. 111 (Draft Record of Decisions of the Meeting of Canadian Blood Committee, February 4-5, 1986); and

Ex. 736, Tab 50 (Letter from Mr. G. Weber to Dr. Leclerc-Chevalier, March 7, 1985).

<sup>125</sup> Evidence of Mr. Stephen Dreezer, former member of the CBC Panel, p. 35461.



CBC on matters related to their role as the policy developers for the Canadian blood system.<sup>126</sup> The secretariat also acted as support to the various CBC committees, which included, an Executive Committee, an Advisory Sub-Committee, a Program and Finance Committee, a Budget Sub-Committee, and a Sub-Committee on Systems.

91. The CBC members were each accountable to their own health ministries. There was no appeal mechanism from any decision made by the CBC. On national issues, the CBC operated on the basis of consensus. The CBC required unanimity of all provinces and the federal government in order to reach a decision. As stated by Ambrose Hearn, a Chairman of the CBC, obtaining such consent could be a challenge.<sup>127</sup> If a policy or funding decision required a significant commitment by the provinces and territories, a number of CBC members had to first consult their Treasury Board and other affected ministries.<sup>128</sup> Consequently, the CBC could not make instantaneous decisions. While consensus decision-making might be appropriate for matters of policy development, it was not ideal for decisions which were time-sensitive.

92. The CBC was to be governed by the four ministerial principles guiding the blood program.<sup>129</sup> In practice, these principles were interpreted by the CBC in keeping with the CBC's role of ensuring the survival of Canadian fractionators. For example, CBC ignored the non-profit principle in ensuring that CLL maintained a profit on fractionated products throughout the 1980's:

MS. EDWARDH: But that (the non-profit principle) is the principle the Ministers chose.

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<sup>126</sup> *Ibid.* pp. 35461-35462.

<sup>127</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, pp. 35383-35386.*

<sup>128</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, pp. 35425-35427.*

<sup>129</sup> *The purpose, as stated in the terms of reference of the CBC of that body was: "To direct the Canadian blood system in accordance with the principles established by the Ministers of Health for the therapeutic use of blood, blood products or its substitutes."*



MR. HEARN: Yes, it is. But even the Ministers would recognize this was an inconsistent principle, because in every other contract that the Red Cross had with every other organization that was providing services to it, there was a profit element.

It was just in the fractionation of blood, and that is because it was an issue that the Ministers were fixed on.

THE COMMISSIONER: Mr. Dreezer, I can understand the point that you make and your position. I don't quarrel with it, but I have a difficulty in understanding the connection between them. Let me be a little clearer.

You say the contract between the Red Cross and Connaught was a matter of interest, fell within the jurisdiction of the Canadian Blood Committee?

MR. DREEZER: That is correct.

THE COMMISSIONER: The other contract was not a contract between those parties, it is between different contracted parties, the province of Ontario and Connaught?

MR. DREEZER: Correct.

THE COMMISSIONER: And, therefore, what they chose to do together was not of any interest, or not the business of the Canadian Blood Committee. If the Province of Ontario wanted to give Connaught \$10 million, or subsidize their operation, that is not a concern of the Canadian Blood Committee?

MR. DREEZER: My recollection is that it was not a concern of the Canadian Blood Committee at the time.<sup>130</sup>

...

MR. HEARN: Sure. The contract relating to the fractionation of blood was intended to be done on a not-for-profit basis, which meant that in the negotiations between the Red Cross and Connaught, it was necessary for Connaught to be -- for that contract in terms of the exchange of funds and so on, to reflect a not-for-profit arrangement. Connaught wouldn't sign a contract if that was the total amount to be paid.

So the Province of Ontario said, "We insisted that this contract be in place. We insist that the blood that is provided, that is in Ontario be fractionated in Ontario. We will now put Connaught in the position so it can sign this contract and have the resources that it needs to continue on with its business."

The important thing for the CBC in terms of principle of the Ministers, was that the amount that was being provided for the fractionation of blood, be in the

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<sup>130</sup> Evidence of Stephen Dreezer/Ambrose Hearn, former Chairman, former members of the Canadian Blood Committee, pp. 35555-35556.



same position as it would have been had Connaught been a not-for-profit company.<sup>131</sup>

93. The absence of a definition of "self-sufficiency" in the guidelines or a national blood policy enabled the CBC to support the political goals of the Ministers of Health. It interpreted sufficiency as the capability to produce blood fractions in Canada (rather than self-sufficiency in terms of plasma collection), in order to try to ensure the survival of the three Canadian fractionators.<sup>132</sup>

94. The interpretation of the self-sufficiency principle in this manner lent itself to denying CRCS the resources necessary to obtain Canadian self-sufficiency in plasma collection; a matter which the CRCS viewed as basic to self-sufficiency. The CBC denied the request of the CRCS to expand its plasmapheresis program in order to eliminate or reduce the reliance on supplementary purchases of plasma from paid foreign sources, on the basis that supplementary purchases were more economical:

While contributing to Canadian self-sufficiency in Factor VIII, such a production level would also contribute to a growing inventory of albumin. To secure and maintain adequate albumin and to safeguard against variable turnaround time from fractionators in the face of unpredictable utilization increases related to the introduction of a 5% Albumin solution, the Red Cross argued for sustaining the program at approximately 12,000 litres of plasma or 24,000 procedures. Moreover, it argued that hospital use of plasma continues to grow and self-sufficiency in Factor VIII should be pursued.

These advantages have to be weighed against the high cost of plasma procurement plus the costs of plasma processing and the cost of sustaining or increasing already high inventory levels of other products.

...Aside from Factor VIII, therefore, there appears to be no need to expand plasma procurement significantly beyond current levels, unless the CBC decides to pursue Factor VIII self-sufficiency more aggressively and until immunoglobulin requirements are more clearly defined through a market survey.

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<sup>131</sup> Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, p. 35560.

<sup>132</sup> Evidence of Mr. Dreezer, former member of the CBC Panel, pp. 35925-35927;

[For example, Mr. Dreezer testified that one of the reasons for the extraordinary assistance package going to CLL for the heat-treatment process was that they had made the point, "Look, if you don't give us some money to help us through this period, we are going to have to break up our teams, and you can kiss your Canadian fractionation capability goodbye."]



The program recommended herein has reduced the pheresis plasma procurement program. A plasma production level of approximately 154,000 litres should be achieved, which is 7,000 litres above the minimum required to meet 1983 plasma fractionation contract commitments and avoid plasma penalties. A supplementary purchase of approximately 22,000,000 million units is required again for 1983. Supplementary commercial purchasing is comparatively less expensive than mounting a major domestic plasma procurement/fractionation program. Until fractionation plans for 1984 and beyond become clearer, this appears to be the most prudent and cost-effective course to follow.<sup>133</sup>

b) **CBC Advisory Sub-Committee**

95. In order to advise the CBC on scientific matters, it was envisaged that the CBC would have a technical advisory sub-committee.<sup>134</sup> The CBC considered two different approaches to such a committee:

Two approaches come to mind in discussing the membership. The first would be to conceptualize the different aspects of collection, processing, distribution, utilization, licensing, etc., of blood and blood products and invite recognized experts in each area to sit on the TSA Committee.

The second approach would be to list the various organizations and associations that have expertise in the blood area and invite representation (e.g. from Canadian Red Cross, CMA, Hematology and Pathologists Association, Bureau of Biologics, etc.). Further consideration could be given to regional balance in the representation. Considerable overlap may exist in the two approaches. However, there are also significant differences. A representative from a particular association is normally in an elected position (e.g. President), who may or may not be considered especially knowledgeable in that particular area of the blood program/system where expertise is desired. Also, one organization (e.g. CRC) may have "experts" in a number of areas, and a "representative" rather than "expertise" approach could limit this input. On the other hand, if extensive use is planned of sub-committees or task forces of the TSA Committee, then a "representative" approach to membership allows for easier recruitment from the ranks of the TSA Committee member associations and organizations.

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<sup>133</sup> Ex. 858, Vol. 190, Tab 14, pp. 290-291 (1983 Recommended National Blood Program - A Report to the Canadian Blood Program (Programs and Finance Committee), dated March 3, 1983).

<sup>134</sup> Ex. 858, Vol. 190, Tab 7, p. 139 (See Terms of Reference of the Advisory Sub-Committee to the CBC, Minutes of the First Meeting of the Advisory Sub-Committee to the CBC, August 25, 1982).



The CBC may also wish to decide whether "disease" associations (e.g. Canadian Hemophiliac Society) should be on the TSA Committee.<sup>135</sup>

96. Ultimately, the CBC decided to adopt the representative approach.<sup>136</sup> Notwithstanding the recognition that the committee could draw on the expertise of the various organizations by way of sub-committee and task force, the CBC never asked the Advisory Sub-Committee to do so.<sup>137</sup> The Advisory Sub-Committee representatives were selected as nominees of the organizations requested by the CBC to take part.<sup>138</sup> The Committee was chaired by a member of the CBC. The CBC did not ask members of the American Red Cross, or other international organizations to attend the meetings of the Advisory Sub-Committee.

97. The CBC invited Canadian fractionators, some of whom were not fractionating any blood product, to sit on this sub-committee. American fractionators were excluded, notwithstanding the fact that American fractionators were fractionating a majority of CRCS plasma and were the most knowledgeable and up-to-date on fractionation techniques.<sup>139</sup>

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<sup>135</sup> Ex. 858, Vol. 190, Tab 3, pp. 19-20 (Paper entitled, "Technical and Scientific Advisory Committee to the Canadian Blood Committee"); and

*Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, p. 35352.*

<sup>136</sup> Ex. 858, Vol. 190, Tab 4, pp. 42-43 (Draft Record of Decisions of Canadian Blood Committee, March 4, 1982).

<sup>137</sup> *Evidence of Drs. Koopman and Langley, former members, CBC Advisory Sub-Committee Panel Members, p. 36305.*

<sup>138</sup> *Evidence of Drs. Koopman and Langley, former members, CBC Advisory Sub-Committee Panel Members, pp. 36563-36564.*

<sup>139</sup> Ex. 858, Vol. 190, Tab 6, p. 89 (Draft Record of Decisions of the Canadian Blood Committee, June 17, 1982).



98. The Canadian fractionators continued to sit on the Advisory Sub-Committee as late as October 1990, despite the fact that none of the three fractionators were producing albumin, Factor VIII, or Factor IX.<sup>140</sup> In fact, Institut Armand Frappier had not even built its fractionation plant by this date.

99. The CBC expected its Advisory Sub-Committee to be a primary source of information on the Canadian blood system:

MS. EDWARDH: ...I draw from at least what you have said, Mr. Hearn, that you expected it to be to some extent, the eyes and ears of what was happening in the -- both from a consumer and from a medical perspective, and that they could alert the committee to issues and changes that were important?

MR. HEARN: Yes.

MS. EDWARDH: So it was designed to be pro-active. It was designed to not only give you advice when you asked for it, but to get information?

MR. HEARN: Yes. It wasn't designed to be decision-making, it was a group that was designed to be consultative within the group, but also to respond to questions that were put to it, or to bring issues forward as the case may be.<sup>141</sup>

100. Notwithstanding the important role that the CBC placed on the Sub-Committee, it was only scheduled to meet twice per year.<sup>142</sup> Further, the CBC offered no resources or assistance in research or preparation of materials for these meetings.<sup>143</sup>

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<sup>140</sup> Ex. 869, Vol. 201, Tab 2 (*Record of Decisions of the 13th Meeting of the Advisory Sub-Committee to the Canadian Blood Committee, October 29, 1990*); and

*Evidence of Dr. Langley, former member, CBC Advisory Sub-Committee Panel Member, p. 36299.*

<sup>141</sup> *Evidence of Mr. Ambrose Hearn, former Chairman, Canadian Blood Committee, pp. 35457-35458.*

<sup>142</sup> *Evidence of Dr. Langley, former member, CBC Advisory Sub-Committee Panel Members, p. 36306.*

<sup>143</sup> *Evidence of Drs. Langley and Koopman, former members, CBC Advisory Sub-Committee Panel Members, p. 36321.*



101. The members of the Sub-Committee, did not view themselves primarily as a group being the "eyes and ears" of the CBC. Rather, they saw their role more as a discussion group:

LANGLEY: I would have to go back to our consensus, that we would be a discussion group. I mean, that was the discussion -- after all of this discussion the first meeting, that is what we concluded, we would be a discussion group or forum for the members of the committee to bring their concerns forward. And that went with the minutes to the CBC. And at the next meeting that we had, the reports came back from CBC. There was no objection, that that is how we would exercise our responsibility.<sup>144</sup>

102. The CBC did not provide its minutes to its Advisory Sub-Committee or to the CRCS. Accordingly, the Advisory Sub-Committee did not have full comprehension of the issues being discussed at its parent committee.<sup>145</sup> It is not clear from the evidence whether or not all the issues that were discussed at the CBC Advisory Sub-Committee were brought to the full attention of the CBC. The CBC had to rely on the chairman of the Advisory Sub-Committee, for whom membership in the CBC was a part-time role, or the secretariat which was critically understaffed.

103. Despite the weakness in the Advisory Sub-Committee, the CRCS attempted to be as helpful as possible in expediting the consensus process. Dr. Perrault provided the CBC Advisory Sub-Committee with a great deal of technical information to assist in making its decisions:

MR. SOKOLOV: What role did Dr. Perrault play in these discussions? Did he play any larger role than other members of the sub-committee?

DR. KOOPMAN: I would say that Dr. Perrault stood out as someone who was extremely knowledgeable and presented a lot of material. There was, I think, no meeting where he did not present something. And he was associated with a lot of propositions and motions, but he was also a listener. He was a man who -

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<sup>144</sup> Evidence of Dr. Langley, former member, CBC Advisory Sub-Committee Panel Members p. 36299.

<sup>145</sup> Evidence of Dr. Perrault, former National Director BTS, p. 30603.



- he was easy to talk to, and we went to him because he had such great knowledge of the blood system for question and advice and maybe for propositions. And he listened to us and then say: "Well, bring it back next time. I have something on that." So he was a resource person, as well.<sup>146</sup>

105. The CRCS actions and opinions were aired, debated and challenged at the Advisory Sub-Committee:

MR. ELLIOT: ...I take it from your evidence that you did not see it as the role of your sub-committee or advisory committee, to second guess the scientific decisions of the Red Cross?

DR. LANGLEY: Well, in our -- I have trouble with the words "second guess". But "question" would that substitute -- question what they were doing? If the Red Cross brought an item for discussion, then we could challenge the data they presented.

If somebody else presented an item for discussion and the Red Cross had an opinion about it, whoever was their representative at the time, then we could challenge that.

So I don't know if we ever got into a position that we were afraid to ask them or challenge them, or that sort of thing. I mean, we respected, as I said earlier today, and I don't want to repeat that, the feeling we had about their scientific expertise. We could be pretty crotchety at times.<sup>147</sup>

106. Notwithstanding the structural weaknesses inherent in the Advisory Sub-Committee, numerous members of this committee were well-placed to bring information forward to the attention of others in the group. For example, on October 30, 1984, the following people were represented at the Advisory Subcommittee:<sup>148</sup>

- Dr. J. Bowman of the Winnipeg RH Institute;

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<sup>146</sup> Evidence of Dr. Koopman, former member, CBC Advisory Sub-Committee Panel Member, pp. 36327-36328.

<sup>147</sup> Evidence of Dr. Langley, former member, CBC Advisory Sub-Committee Panel Member, pp. 36521-36522.

<sup>148</sup> Ex. 860, Vol 192, Tab 2 (October 30, 1984 Record of Decisions of the Fifth Meeting of the Advisory Sub-Committee to the Canadian Blood Committee).



- Mr. G. Cossette of Connaught Laboratories Limited;
- Dr. M. Inwood of the Canadian Hematology Society (also a member of the CHS MSAC);
- Dr. P. Coutman of the Canadian Medical Association;
- Dr. R. Langley of the Canadian Cancer Society;
- Mr. K. Poyer of the Canadian Hemophilia Society;
- Mr. N. Simonieu of the Canadian Hospital Association;
- Dr. W. Boucher of the BoB;
- Mr. W. Read of the Canadian Hemophilia Society.

107. While the Advisory Sub-Committee could have assisted in the formation of a national blood policy, the CBC decided to retain this initiative:

MR. SOKOLOV: Now, from your perspective as members of the Advisory Sub-Committee and as consulting parties in the formulation of this blood policy, can you offer any insight as to why it did not succeed? And Dr. Langley, I will ask you first.

DR. LANGLEY: I don't know. It was the sort of test that was just the sort of thing the Advisory Sub-Committee could have done. I mean, we didn't have the expertise for a lot of the technical things that go on. But this was something, this kind of big global issue that we could have taken on, we felt competent to do and we even requested to do it.

On the other hand, you just wonder if the people -- there is so many nuances to it. I mean, I wouldn't understand the issues from the fractionation point of view, but with three fractionators there and them debating it, you will be able to pick out the truth, until you got a consensus. I wonder, would the Deputy Ministers of Health's representatives from the provinces have the expertise to develop a National Blood Policy.

I think eventually they turned to the Red Cross to kind of almost do it for them at that level, but I would think they would have great difficulty. It is a very complex -- plus our health system is provincially based. Would that have been a reason?

MR. SOKOLOV: Dr. Koopman, do you have any insight as to why this effort, which was a matter of some urgency in 1982, became bogged down and ultimately could not succeed?

DR. KOOPMAN: I don't have any recollection why it got bogged down. I would have thought that there would certainly be some people in the group that could make good propositions that could have formed a very good nucleus proposition, and that was the Red Cross but they were turned down at the beginning. So I guess the remaining players were just not up to it. That was my evaluation of it.<sup>149</sup>

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<sup>149</sup> Evidence of Drs. Koopman and Langley, former members, CBC Advisory Sub-Committee Panel Members, pp. 36475-36476.



5) National Blood Policy

108. The need for a national blood policy has been recognized since the 1970's<sup>150</sup> and has been recognized by bodies such as the CRCS, CBC, the Federal/Provincial Ad Hoc Committee on Plasma Fractionation and the Advisory Sub-Committee to the CBC.<sup>151</sup>

109. Canada lags behinds other western industrialized nations in its failure to have a national blood policy.

MS. EDWARDH: ...I mean how alone are we having failed to come to grips with this issue?

MR. WEBER: Well, we are, to the extent of being alone on that, because a number of years ago and I can't recall the exact year, whereby WHO had done a survey looking for what countries trying to get the -- collect the blood policies, and I recall because it was during my term of office as Secretary General of the Canadian Red Cross, us urging the -- either it was the CBC or the Canadian Blood Agency to at least respond to that request, because we had picked it up in other circles. And Dr. Perrault attending other international meetings of the international group of blood experts of the Red Cross/Red Crescent, other areas that Canada hadn't replied to a request from WHO to say where we stand with a national blood policy. And we were, as Canadians, somewhat embarrassed by that fact....

MS. EDWARDH: Now, of other -- if you compare Canada then to other western industrialized countries, can you give some sense of how -- are their policies comprehensive in the sense that they look at roles and responsibilities and accountabilities, et cetera?

MR. WEBER: Most do. In terms of setting out what is the overall system in terms of roles, responsibilities, authorities and accountabilities. And I think that that gives you some clarity so that everybody knows what they are supposed to do, and know what they are accountable for.

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<sup>150</sup> Evidence of Dr. Perrault, former National Director BTS, p. 30594.

<sup>151</sup> Ex. 736, Tab 4 (Letter from Dr. R. Perrault to Mr. Ambrose Hearn, January 20, 1982);

Ex. 736, Tab 5 (Letter from Mr. Ambrose Hearn to Dr. R. Perrault, February 1, 1982);

Ex. 736, Tab 2, (Federal/Provincial Ad Hoc Committee on Plasma Fractionation Report); and

Ex. 858, Vol. 190, Tab 11, pp. 210-211 (Minutes of the Second Meeting of the Advisory Sub-Committee to the Canadian Blood Committee, December 7, 1982).



MS. EDWARDH: Do you have any sense, and you have given one reason, or one of the benefits of having a policy, but do you have any sense from your colleagues or from those societies that do run full blood programs, about how important they believe this national blood policy is to their functioning?

MR. WEBER: It is fundamental. It is fundamental to their operations. It is clear -- of course, in all these type of situations, there is always a little bit of grey, but it minimized the grey. And the grey, you sit down and you have a reasonable discussion and discussion, and kind of work it out, because in particular if you are dealing with evolving situations, but otherwise, if it is very clear, who was responsible for what, you just get on with doing it. And you are held accountable for the responsibility that you have been given.<sup>152</sup>

110. The effect of the absence of a national blood policy in Canada cannot be overestimated.<sup>153</sup> Dr. Perrault testified that the lack of such a policy affected the budgetary expenditures of the CRCS (in respect of the line-by-line budgetary approval that was undergone),<sup>154</sup> the implementation of quality assurance programs and management information systems,<sup>155</sup> the pursuit of plasma self-sufficiency<sup>156</sup> and funding of research on blood issues.<sup>157</sup>

111. The CBC Advisory Committee also saw the urgency and necessity for a national blood policy:

DR. LANGLEY: Well, it seemed to me there were a number of -- there were policies out there that were being implicitly used that weren't incorporated into a national blood policy, like the protection of the -- going as a volunteer donor system instead of going for a commercial system.

There were potential intrusions, commercial manufacturers wanting to set up autologous blood transfusions and selling the blood. So this would have perhaps

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<sup>152</sup> *Evidence of Mr. George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40444-40446.*

<sup>153</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30593-30596.*

<sup>154</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30596-30597.*

<sup>155</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 30597.*

<sup>156</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 30598.*

<sup>157</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 30598.*



lured people away from the Red Cross donor system into commercials, and the system would have started falling apart.

The manufacturers were concerned about fractionation, should there be one or two or more plants. There was a whole host of issues, that every sort of different group felt that there was a component of a policy that should be there, that they should know, so they could respond to it.

So I think each person had a little different component of it, but in the aggregate there was a feeling we should have a national blood policy, as a fairly urgent matter.<sup>158</sup>

MR. CHERNIAK: Well, is it not fair to say that -- I can't go through all of the decisions that you made, but that it would have been useful to have the overall framework of a policy that you could have - when various matters came to you -

DR. LANGLEY: Yes.

MR. CHERNIAK: -- for decision, you could have looked at and tried to determine how it fit within the policy, and if it fit within the policy, then the decision that you had to make would have become clearer?

DR. LANGLEY: Yes.

MR. CHERNIAK: And the lack of it made it necessary that every decision had to be done on an ad hoc basis, looking at it just on its merits, without an overall framework?

DR. LANGLEY: Yes.<sup>159</sup>

112. The Secretary General of the CRCS also testified as to the need for this policy. Mr. Weber noted that the issue of safety would have been specifically addressed in a national blood policy.<sup>160</sup>

MS. EDWARDH: Well I won't ask you to speculate any more, but I will ask you then to talk about, if you would, the affect in your own mind that the failure

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<sup>158</sup> Evidence of Dr. Langley, former member, CBC Advisory Sub-Committee Panel Member, pp. 36470-36471.

<sup>159</sup> Evidence of Dr. Langley, former member, CBC Advisory Sub-Committee Panel Member, p. 36580.

<sup>160</sup> Evidence of Mr. George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, p. 40458.



to deliver this program or this policy, what were the consequences for the Red Cross?

MR. WEBER: I think the consequences for the Red Cross is that from time to time while we made every effort and continued to make every effort to make the system work. I think that extra effort always needed to be used in terms of dealing with the process and trying to get clarity and trying to push for decisions and building up a dynamic for appropriate decision making. Because you would have to have, you know, build up consensus constantly because things were not clear and try to get the majority to go along with -- that's the way we got to go and that you had the majority to take you for the decision making. It just affected - affected decision making in some respects for certain issues.

MS. EDWARDH: Let me put a couple of propositions to you. Certainly it would appear that in the absence of a blood policy it would be harder for the Red Cross or for any of the other elements in the system to engage in a long term planning?

MR. WEBER: Well, I think the Society itself had some -- was able to do long range plannings as what it thought it should do. But in terms of having -- of our funders to go along with that and in terms of what we would want to do in terms of programming and things of this nature in operations, yes, it made that very, very difficult. Because everybody was going, "Well, is that your role or not role? And where do you consult? When don't you consult?" and so on.

MS. EDWARDH: And do I take it that the absence then of such a policy and the absence of long-term strategic planning for the elements on the system, just generally, would have resulted in the system lacking direction that it could -- lacking the direction, it could have had, had there been a national blood policy?

MR. WEBER: The answer is yes.<sup>161</sup>

113. Finally, it is important to note the CBC's view of the National Blood Policy as recorded in the Minutes of the December 9-10, 1982 Record of Decisions of the Canadian Blood Committee:

Members of the CBC recognized the need and the urgency of developing such a policy, as approved by the Conference of Ministers of Health. However, they did not agree to give Red Cross the responsibility to prepare the working document because it might be perceived as being biased. The Committee also decided to keep the leadership in this activity. Consequently all consultation will be done by the CBC.<sup>162</sup>

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<sup>161</sup> *Evidence of Mr. George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, pp. 40461-40463.*

<sup>162</sup> *Ex. 858, Vol. 190, Tab 13, p. 249 (Record of Decisions of the Canadian Blood Committee, December 9-10, 1982).*



a) **CRCS Proposes A National Blood Policy**

114. The CRCS informed the CBC in writing of its concern about a lack of a national blood policy two months after the CBC was formed.<sup>163</sup> The CBC replied that it shared that concern and welcomed the assistance of the CRCS in developing such a policy.<sup>164</sup>

115. At the second meeting of the CBC Advisory Sub-Committee on December 7, 1982, it resolved to recommend that the CBC recognize the urgency of a national blood policy and take appropriate action for its development. A further motion was carried asking the CBC request the Advisory Sub-Committee to prepare a draft policy.<sup>165</sup>

116. At the CBC meeting of December 9-10, 1982, it was decided that the Advisory Sub-Committee should not prepare the draft policy. The members of the CBC determined that it would retain leadership, consult appropriately and draft the policy itself. All consultation would be done by the CBC.<sup>166</sup> (The members of the Advisory Sub-Committee, however, felt that it was inappropriate for the CBC to be engaged in this task as its members lacked the requisite expertise.<sup>167</sup>)

117. Nevertheless, at the third meeting of the CBC Advisory Sub-Committee, Dr. Martin Inwood suggested that the initial working document be provided under the auspices of the CRCS BTS and the document be brought to the Advisory Sub-Committee for further deliberation. Dr. Perrault noted that the CRCS was willing to lend assistance to the secretariat,

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<sup>163</sup> Ex. 736, Tab 4 (Letter from Dr. Perrault to Mr. Ambrose Hearn, January 20, 1982).

<sup>164</sup> Ex. 736, Tab 5, p. 2 (Letter from Mr. A. Hearn to Dr. Perrault, February 1, 1982).

<sup>165</sup> Ex. 858, CBC Vol. 190, Tab 11, pp. 7-8 (Advisory Sub-Committee to the CBC Minutes).

<sup>166</sup> Ex. 858, Vol. 190, Tab 13, pp. 15-16 (Record of Decisions of the CBC, December 9-10, 1982).

<sup>167</sup> Evidence of Drs. Koopman and Langley, former members, CBC Advisory Sub-Committee Panel Members pp. 36475-36476.



but reminded the committee that the development of the draft itself fell within the mandate of the CBC.<sup>168</sup>

118. In March 1983, the CBC determined that the following elements should be included in the national blood policy:

- the four principles previously enunciated by the Ministers of Health;
- the terms of reference of the CBC and its authorities;
- the applicability of the policy to the CRCS, the fractionators and governments;
- the role and corporate principles of the CRCS and its contractual relationship with governments and hospitals;
- international provisions;
- authority for product standards development, implementation and control;
- authority for policy decisions, implementation, monitoring and appeal;
- recognition of blood as a public, national and limited resource; and
- research and development.<sup>169</sup>

119. At the June 15, 1983 meeting of the CBC, some members of the Advisory Sub-Committee again suggested that the CRCS should develop the national blood policy. The CBC declared that it would retain the lead in the development of the policy and the CRCS would serve in an advisory capacity.<sup>170</sup> A national blood policy was scheduled to be completed and published by 1985.<sup>171</sup>

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<sup>168</sup> Ex. 859, Vol. 191, Tab 1, p. 5 (*Record of Decisions of the Third Meeting of the CBC Advisory Sub-Committee to the CBC, June 14, 1983*).

<sup>169</sup> Ex. 858, Vol. 190, Tab 14 p. 16 (*Record of Decisions of the CBC, March 22-23, 1983*).

<sup>170</sup> Ex. 859, Vol. 191, Tab 2, p. 7 (*Record of Decisions of the CBC, June 15, 1983*).

<sup>171</sup> *Ibid.*



120. The CBC then undertook a series of consultations with various affected groups. Comments from 61 organizations were solicited by the CBC.<sup>172</sup> Two drafts of a national blood policy were prepared by the Secretariat from 1984-89, but neither were adopted.<sup>173</sup> Ultimately notwithstanding the passage of 7 years, no national blood policy was issued by the CBC.

b) The Initiative for a National Blood Policy Ends

121. In 1989, the CBC decided unilaterally to drop the pursuit of a national blood policy. Instead, seven new principles drafted by the CBC Secretariat were presented by the CBC to the Canadian Provincial Health Ministers for their approval.<sup>174</sup> Neither CRCS nor any of the 61 organizations consulted on the formulation of a national blood policy were consulted in the formulation of these seven principles.

We (CRCS) had no official input, and nor did the 41 (sic) organizations that were consulted in the discussion, or the development of the National Blood Policy. There was an extensive round of consultations done, and suddenly we found that these seven principles had been adopted. There is a lot of discussion that follows that point.

Comments were made at the time, by the secretariat staff who developed these principles, as far as I know, that these principles seem to embody the essence of discussions that were held during the round of consultations, but there was certainly no check done with the people consulted.<sup>175</sup>

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<sup>172</sup> *Ex. 859, Vol. 191, Tab 11, p. 028923 (Record of Meeting between CBC Executive Committee and Senior CRCS Officials, August 22, 1984).*

<sup>173</sup> *Ex. 863, Vol. 195, Tab 3, p.144 (Record of Decisions of the Minutes of Meeting of the Advisory Sub-Committee to the CBC, November 20, 1986); and*

*Ex. 654, Vol. 51, Tab 9, p.92067 (Minutes of Meeting between CBC/CRCS staff, October 12, 1988).*

<sup>174</sup> *Ex. 867, Vol. 199, Tab 6, p. 112-113 (Record of Decisions of the Meeting of the Canadian Blood Committee, May 16-18, 1989).*

<sup>175</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30627-30628.*



122. The principles were presented and approved by the Ministers of Health on September 6-7, 1989 notwithstanding the fact that the Ministers did not appear to be expecting them.<sup>176</sup>

123. The seven principles were:

1. The voluntary donor system should be maintained and protected.
2. National self-sufficiency in blood and plasma collections should be encouraged.
3. Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged.
4. Safety of all blood components and plasma fractions should be paramount.
5. Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.
6. A cost-effective and cost-efficient blood system for Canadians should be encouraged.
7. A national blood system should be maintained.<sup>177</sup>

124. The CRCS viewed these seven principles as deficient as they each contained the word "should" in them. In the view of the CRCS, this did not require strict compliance by all participants in the blood system.

DR. PERRAULT: ...We expected there would be some formal consultation so that we could go back to our committees. But by the time we got back to our committees, this was enshrined, and the first comment we had is that if you read those principles, they have one word in common throughout, and it says: the word "should be" rather than "shall".

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<sup>176</sup> Ex. 867, Vol. 199, Tab 8, p. 210-211 (*Record of Decisions of the Meeting of the Canadian Blood Committee, October 4-5, 1989*).

<sup>177</sup> Ex. 880, Vol. 212, Tab 18 pp. 6253-6254 (*Provincial/Territorial Conference of Ministers of Health held in Quebec on Sept 6-8, 1989*).



MR. CHERNIAK: And what was your view of the appropriateness of "should" rather than "shall"?

DR. PERRAULT: Well, it certainly did not give those principles a lot of teeth. Anybody could skate out of that at any opportunity.<sup>178</sup>

125. Following the pronouncement of these seven principles, there was no further effort to develop a national blood policy. The CBC viewed the seven new principles as taking the place of a Canadian national blood policy.<sup>179</sup> The CRCS did not share this view as these principles are silent on the issue of roles and accountabilities.

#### 6) CRCS Mandate/Written Agreement with CBC

126. In the absence of a national blood policy, a legislative framework for the Canadian blood system, or terms of reference that clearly spelled out the roles and responsibilities of the participants in the blood system, the CRCS attempted to secure a written agreement with the CBC to clarify roles and responsibilities.

127. On December 13, 1982, Mr. Tellier, then the Secretary General of the CRCS wrote to Mr. Hearn, Chairman of the CBC, requesting a written agreement that would define the position, authority and limits of responsibility of the CRCS.<sup>180</sup>

128. The CBC did not respond directly to this request until August 23, 1983. On that date, Dr. Leclerc-Chevalier sent a letter to the CRCS noting that:

All members recognized the merits of your request to obtain from governments, through the CBC, a clear definition of the Red Cross position, authority and limits of responsibility within the Canadian Blood System. However, after an

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<sup>178</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30630-30631.*

<sup>179</sup> *Ex. 867, Vol. 199, Tab 8, p. 211 (Record of Decisions of the Meeting of the Canadian Blood Committee, October 4-5, 1989).*

<sup>180</sup> *Ex. 736, Tab 14 (Letter from Mr. Henri Tellier to Ambrose Hearn, December 13, 1982).*



analysis of the points raised in your letter, it was concluded that these elements were also components of a National Blood Policy and, as the development of such a policy has been undertaken by the CBC in conjunction with the Canadian Red Cross Society, governments and all health agencies and groups involved or interested, it was judged premature to provide an answer to your question at the present time and found preferable to consider the issue within the broader context of a Canadian Blood Policy.<sup>181</sup>

129. On May 1, 1984, the CRCS again raised its request for a definition of the management role of the CRCS at a meeting between the CBC Executive and Senior CRCS officials. At this meeting, the CBC was disciplining the CRCS for purchasing a VAX computer without prior approval by the CBC.<sup>182</sup> Mr. Hare (the acting Chairman of the CBC) informed the CRCS that efforts were underway to determine roles and accountabilities and further commented that it would be to everyone's advantage to have this done as soon as possible. The CBC assured the CRCS that all possible efforts would be made to deliver comments to the CRCS on their December 13, 1982 letter.<sup>183</sup> Despite this assurance, the CRCS never received any comments from the CBC on its proposal for an agreement.

130. Following its post audit review of the National Blood Program for the years 1982-1985, Touche Ross recommended that there be a formal agreement between the CRCS and the CBC. In its comments concerning the Touche Ross audit to the CBC, the CRCS stated:

We know the process of developing a National Blood Policy may take in excess of one year. We suggest that formalizing arrangements should not wait that long, as the areas of uncertainty outlined in the Touche Ross report will not enhance good management of the Society's Blood Programme.<sup>184</sup>

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<sup>181</sup> Ex. 736, Tab 19 (Letter from Dr. Denise Leclerc-Chevalier to Mr. Henri Tellier, August 23, 1983).

<sup>182</sup> This issue is fully discussed in Section B(7)(d).

<sup>183</sup> Ex. 736, Tab 35 (Meeting between the CBC Executive and CRCS Officials, May 1, 1984).

<sup>184</sup> Ex. 865, Vol. 196, Tab 3 p. 004882 (Appendix I to Letter from Dr. Perrault to Dr. D. Leclerc-Chevalier Re: Touche Ross Report, dated April 27, 1987, p. 04881).



131. There was no response from the CBC with respect to the formalization of the relationship between the CRCS and the CBC. No formal agreement was ever signed.<sup>185</sup>

132. The absence of proper terms of reference, a national blood policy, or a written agreement between the CBC and CRCS caused uncertainty and confusion in the blood system. Frequently, the CBC acted as the *de facto* manager of the blood system contrary to the professional judgment of the CRCS. In a position paper written in December, 1985, Dr. Perrault summarized the situation as follows:

In 1982, we felt that the role of the Canadian Blood Committee could well evolve towards that of a "Management Board" for the Blood Programme: this was raised in the C.R.C.S. April 1982 response to the C.B.C terms of reference....

What are the exact decisions that the C.R.C.S. can make? Number of staff appointments, rate increases, increases in the use of supplies and allocations of equipment, programme expansion (eg. plasmapheresis), choice of fractionators, conditions under which fractionators will be paid, etc. are all areas where C.R.C.S. has very little choice in the matter. The choice between one supplier and another is subject, in certain circumstances, to the political processes of the governments.<sup>186</sup>

133. The effect of this management control by the CBC was further discussed in a 1988 CRCS position paper wherein the CRCS commented upon the achievements of the CBC from its inception. The paper noted:

1. The development of a Canadian Blood Policy was one of the mandates given to the Canadian Blood Committee by the Conference of Ministers of Health in 1980. The other mandates were to oversee the blood program of the Canadian Red Cross Society, and the development of three Canadian Fractionation Plants.
2. To date there is no functioning Canadian fractionation plant, and no Blood Policy that can be operationalized. The only mandate that is carried out by the CBC is the oversight of the Blood Programme of the Canadian Red Cross Society.

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<sup>185</sup> Evidence of Mr. Robert Gamble, former Chair CBC, pp. 38615-38613.

<sup>186</sup> Ex. 736, Tab 46, p. 3 (Position paper by Dr. Perrault, former National Director, BTS, December 2, 1985).



3. In the absence of a Canadian Blood Policy the following problems have accumulated:

- a) Canada is almost 100% dependent on foreign (mostly) US fractionation of plasma.
- b) 50 - 70% of plasma products used in Canada are produced from plasma of foreign, commercial donors.
- c)
- d) Blood products are regulated by the Food and Drug Act but there is currently no licensing requirement in Canada other than for plasma pheresis and cell pheresis.
- e)
- f)
- g)
- h) The National Reference Laboratory is now funded at the same level as it was 10 years ago. The reputation of this institute has all but vanished.
- i) Budget decisions made by the Canadian Blood Committee allow for no growth whatsoever. Some decisions are highly questionable, e.g. a staff cut in Central Ontario BDR.
- j) The Federal Minister of Health is misinformed about Red Cross and the Blood Programme. We do not know about the status of provincial Ministries of Health.<sup>187</sup>

134. These conclusions were confirmed in the August 1989 report of the Deputy Minister's working group studying plasma fractionation in Canada. This working group was chaired by Mr. Robert Gamble, the Chairman of the CBC. In its report the group identified five key concerns in the operation and mandate of the CBC. These were:

1. There is no single legally accountable entity that could act with authority (on behalf of all the governments of Canada):
  - to operate directly or indirectly a national blood program,
  - to enter into any legally binding contract related to the operation of a national blood program...
2. The current management system lacks well defined responsibilities and legal authorities for all participating organizations...
3. The lack of clear authority by one organization also has implications with respect to the very real liability concerns...

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<sup>187</sup> Ex. 737, Tab 11 (Position paper by the CRCS, July 19, 1988).



4. The separation of funding responsibility from the management decisions of the CRCS inevitably results in governments becoming involved in some day-to-day management issues and the CRCS being unable to pursue corporate objectives due to lack of financial resources under direct control.
5. The National Blood Program operates as a national program in a provincially run health care system. This fact creates unique problems in the management of the system, involving the approval and funding authorities for program and policy changes.<sup>188</sup>

135. The Gamble working group identified a number of similar concerns which the CRCS had raised in its 1982 commentary on the CBC's terms of reference.

#### 7) Funding of the Blood Program

136. From 1982 to 1990 the provinces funded 100% of the BTS and 80% of the BDR budget.<sup>189</sup> The CRCS was accountable to the provinces for the money it received to run the blood program. This accountability was tightly enforced by the CBC through its budgetary review process.

##### a) **BDR Funding**

137. The BDR budget was formulated at the Divisional level and approved by the Divisional Commissioner. Allocations within BDR varied with the characteristics of each province. Mr. Morin described it as follows:

...I have always had concerns about this because we had the blood donor recruitment provincially administrated and managed and a national blood program that was nationally managed and administered. And this had for an impact that there was no national standards for BDR and their allocating costs

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<sup>188</sup> Ex. 737, Tab 23 (*Final Report of the Ad Hoc Working Group, August 25, 1989*).

<sup>189</sup> Ex. 736, Tab 7, p. 11 (*Canadian Blood Committee Draft Terms of Reference Commentary by the Canadian Red Cross Society, April 12, 1982*).



or other usage as we could implement in the National Blood Transfusion Service. Therefore, yes, the commissioners of each provincial division, was left on their own to allocate their overhead to all of their programs including the BDR.

This however, I have got to qualify that speaking with the commissioners on a continuous basis about that, they always had their rationale to justify their actions. But it was -- I can't imagine that it would have been difficult for the people having the responsibility to approve these budgets, and sitting and looking at one province going one way and then the other province going the other way. And yes, a lot of questions were raised on that... I can try to make you understand why this could have happened. And if you had for instance, a province like Ontario structured with five blood centres, that meant five regional BDR to satisfy or to service these five blood centres.

Quebec had two blood centres therefore, they had a need for BDR staff to satisfy two blood centres. So what was the big question all the time was "How come is Ontario staffed so heavily on the high management level and low clerical work as opposed to Quebec, being financed with low management level and high clerical -- ", and these were the comparisons that were coming to me all the time...

I would like also to maybe take this opportunity, Mr. Commissioner, to say that I have always had the assurance I should say, that the governments -- provincial governments have been very well served with the blood donor recruitment irrespective of some -- maybe some deviations here and there.<sup>190</sup>

138. While the CRCS paid 20% of the BDR costs out of its own funds, this contribution did not account for the "non-financial" contributions of its volunteers which Mr. Morin estimated could amount to \$50 million per annum:

In late 1970s, early 1980s, I had attempted to try to cost what would be the real work of the Blood Donor Recruitment in provinces as opposed to what really it is that we are paying for. And I tried to estimate for instance, media cost. It is absolutely free, by all medias in Canada. That is a value of roughly 10 million dollars. What about the value of all the volunteers in the Red Cross coming in and organizing these Blood Clinics and giving their time, serving coffee, providing doughnuts and often doughnuts made home and not purchased at the store.

What about the Coca-Cola Company, providing all the soft drinks to the Red Cross volunteer side? What about the corporation providing free time to their staff to go and give blood? There was a cost there. What about these other

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<sup>190</sup> Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39869-39871; and

Ex. 881, Vol. 213, Tab 13, p. 052370 (Briefing Book on the Canadian Blood System, April, 1991).



places where we were getting these locations to organize a blood clinic free of charge because it was the Red Cross.

When one looks at all of that, and yet all of that would have been paid, I had come to -- very close to 50 million dollars at that point in time. And the cost that we have right now in front of us is about 10 million -- 8 to 10 million.

So we are looking at a very good, very serious arrangement here with having the Red Cross organizing and go and get its blood donors. Give your blood to the Red Cross, and that works.<sup>191</sup>

139. The BDR funding process entailed the same rigorous scrutiny by the provinces as did the BTS budget.<sup>192</sup>

b) **BTS Funding**

140. BTS funding was comprised of 2 elements: the BTS budget and the fractionation account.

i) **BTS Budget**

141. At the request of the CBC to enable it to more fully understand funding trends, the BTS budget was in fact two budgets: an "A" budget that detailed ongoing programs approved in previous budgets; and a "B" budget that detailed new program initiatives.<sup>193</sup>

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<sup>191</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS. pp. 39871-39872.*

<sup>192</sup> *Ibid. p. 40014.*

<sup>193</sup> *Ex. 858, Vol. 190, Tab 6, p. 90 (Record of Decisions of Meeting of the Canadian Blood Committee, June 17, 1982).*



142. Once a budget was approved, funds were paid to the BTS monthly or bi-weekly by each province.<sup>194</sup> Any adjustment to this cash flow required formal budgetary approval by the CBC.<sup>195</sup>

143. Even after budgetary approval, major funding provinces frequently delayed adjusting their funding level, forcing the CRCS to incur financing charges.<sup>196</sup> In 1983, the CBC and CRCS agreed that financing charges for the blood program would be borne by the CRCS. As a corollary, interest accumulated on unspent funds would be retained by the CRCS.<sup>197</sup> This system was implemented to encourage good cash management practices on behalf of the CRCS. While this arrangement was never formalized, it met with the full agreement of the CBC.<sup>198</sup>

144. The CBC utilized a "slip-year" to account for over-expended or unexpended funds in a given budget year.<sup>199</sup> Money not spent or deficits incurred in year-0 were retained (with financing costs or interest) in year-1 and accounted for in year-2. Any unexpended funds in year-2 reduced the amount of money payable by the provinces for that year. Any over-expenditure by the CRCS required justification. If approved, the CBC increased money payable

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<sup>194</sup> *Ex. 881, Vol. 213, Tab 13, p. 052382 (Briefing Book on the Canadian Blood System, April, 1991).*

<sup>195</sup> *Ibid; and*

*Ex. 858, Vol. 190, Tab 4, pp. 49-50 (letter from Mr. Ambrose Hearn to Henri Tellier, March 4, 1982).*

<sup>196</sup> *Ex. 868, Vol. 200, Tab 1, p. 2 (Minutes of the Meeting of the CBC Budget Sub-Committee, November 22, 1989).*

<sup>197</sup> *Ex. 864, Vol. 196, Tab 4, p. 164 (Letter from Dr. Perrault to Dr. Leclerc-Chevalier, April 27, 1987); and*

*Ibid, Tab 3, p. 93 (Minutes of the CBC/CRCS Meeting dated April 24, 1987).*

<sup>198</sup> *Evidence of Mr. Robert Gamble, former Chair CBC, pp. 38612-38613; and*

*Evidence of Mr. Claude Morin, former National Administrator CRC BTS, p. 40016.*

<sup>199</sup> *Evidence of Mr. Robert Gamble, former Chair CBC, pp. 38612-38613.*



to the BTS for the over-expenditure.<sup>200</sup> Approval was also required if CRCS purchased an "unbudgeted product or service" even if it came within the funds allotted for its global budget.<sup>201</sup> The CRCS was instructed by the CBC not to utilize any surplus funds during the slip year.<sup>202</sup>

145. Any interest which accumulated on surplus funds was used by the CRCS to decrease the cost of its national office overhead. As the national office oversaw the blood program as well as other non-blood-related programs, national office expenses were allocated between the blood program and other non-blood related programs. Approximately 2/3 of the cost of the national office was attributed to the blood program i.e. if the national office purchased a photocopier for \$900, \$600 would be expensed to the blood program and \$300 would be allocated to other programs such as international relief or water safety. Consequently, 2/3 of any funds dedicated to the national office outside of funds attributed from other programs (such as the interest on surplus blood program funds) would go to the benefit of the blood program.<sup>203</sup>

#### ii) Fractionation Account

146. The funds used to pay for fractionation and fractionated products were treated differently than BTS funds. The fractionation account was a device by which the CRCS held funds on behalf of the provinces. Accordingly, funds in this account were listed in the CRCS books as an account payable.<sup>204</sup>

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<sup>200</sup> *Ex. 881, Vol. 213, Tab 13, p. 13 (Briefing Book on the Canadian Blood System, April, 1991).*

<sup>201</sup> *Ibid.*

<sup>202</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 28198 - 28202 .*

<sup>203</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39847-39848.*

<sup>204</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39883-39884.*



147. Unlike BTS, the fractionation program was funded on a "pay-as-you-use" basis. The amounts billed for these products encompassed both processing and distribution costs. Provinces were billed on a monthly basis based on product deliveries to hospitals.<sup>205</sup> Prior to 1982, the provinces did not reimburse the CRCS for any financing costs incurred in running this program. Since 1983 (after a \$600,000 settlement to resolve past financing charges) financing costs were included in to the cost of these products to the provinces.<sup>206</sup> The CRCS had no authority to use funds in the fractionation account without prior approval from the CBC.<sup>207</sup> Unlike the BTS account, the CRCS could not retain interest nor were they required to pay the financing costs, of any surplus/deficit in the fractionation budget.

148. A margin representing the cost of BTS research and development was built into the price charged to the provinces and paid out of the fractionation account.<sup>208</sup> With the approval of the CBC, this margin was increased to allow working capital to accumulate in the account in order to allow the program to be self-financing in the future.<sup>209</sup> While some working capital did accumulate, it never reached the point where the account was self-financing.

149. The CBC used the fractionation account for purposes unrelated to the specific fractionation of product. Through the budgetary process, funds were allocated towards the implementation of the CRCS Blood Information System and for BTS Research and

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<sup>205</sup> *Ex. 957, Vol. 288, Tab F, p. 327 (Post-Audit Review of the National Blood Program of the Canadian Red Cross Society by Touche Ross, January, 1987).*

<sup>206</sup> *Ibid, p. 327.*

<sup>207</sup> *Evidence of Mr. Klotz, CBC Panel, pp. 36871 - 36872.*

<sup>208</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39897-39898.*

<sup>209</sup> *Ibid, pp. 39894-39895.*



Development.<sup>210</sup> In 1985 (outside of the budget approval process) the CBC instructed the CRCS to forward funds to CLL as part of a "relief package." This was done without prior approval by the provincial Ministries of Health.<sup>211</sup>

### c) Budget Approval Process

150. Budget approval of the CRCS blood program was a long and detailed process. The level of detail required by the CBC entailed extensive preparation by the CRCS. It was subject to intense scrutiny by the secretariat and the CBC. Because of the limited resources of the secretariat and the level of detail required, at no time did the CBC approve the CRCS budget by the beginning of its fiscal year. This had a serious detrimental effect on the CRCS blood program as the CBC did not permit the CRCS to engage new staff or implement new programs until formal budgetary approval was provided. A delay was always occasioned due to the fact that this approval was not given until after the beginning of the fiscal year.<sup>212</sup>

151. Between 1983 and 1986 the CRCS formally submitted its budget in September, prior to the commencement of its fiscal year on January 1st. The budget would consist of the consolidated BDR budgets, the fractionation budget and the BTS "A" and "B" budgets. Quebec CRCS required a separate budget until 1983 when Quebec became a member of the CBC.

152. The CBC required costs to be broken down on a line-by-line basis. Line items were required on both a provincial and a centre-by-centre basis. All changes in expenditures from prior years required clear identification and written justification. An executive summary.

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<sup>210</sup> *Ibid.*, pp. 39897-39898.

<sup>211</sup> *Ibid.*, p. 39898; and

*Ex. 860, Vol. 192, Tab 10, p. 244 (Record of Decisions of Meeting of the Executive Committee of the Canadian Blood Committee, April 17, 1985).*

<sup>212</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39775-39776; and*

*Evidence of Dr. Perrault, former National Director BTS, p. 30310.*



financial summary and program summary were attached to budgets. Any new program or expenditure was to be specified in its "B" budget and each element justified as a line item.<sup>213</sup>

Mr. McNaught, former Chairman of the FPPBRC explained the methodology used for the financial review of the CRCS submission:

...it has been a line-by-line review, centre-by-centre (except in Quebec), with comparative analysis, taking into consideration the volume parameters both for BDR and BTS. Breaking down by category of expense, a staff review was done by province, by program and by category of personnel. Applicable provincial wage restraint policies were applied, taking into consideration existing contract obligations.<sup>214</sup>

Likewise, Mr. Morin described the process as follows:

It was a line by line budget. What I mean by line by line, I mean exactly that. The most little item, the most little amount of money had to be accounted for.<sup>215</sup>

153. In preparation of its formal budget, the CRCS National Office would thoroughly vet budget submissions from, *inter alia*, the 17 regional centres, the National Office, NRL, and Blood Product Services. In total, the BTS administration dealt with 118 separate budgets.<sup>216</sup> Requests were evaluated and the budget was then recast in a format that was hoped to be acceptable to the CBC.<sup>217</sup>

When one looks at the preparation of the budget by the blood program of the Red Cross, one will realize it that took anywhere from five to six months. And, therefore, before putting things together, there was a lot of contact, and

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<sup>213</sup> Ex. 882, Vol. 214, Tab 1 (*Canadian Red Cross Society Blood Programme 1985 Proposed Budget presented to the Canadian Blood Committee*); and

Ex. 858, Vol. 190, Tab 4, p.46 (*Letter from Mr. Hearn to Mr. Tellier, March 4, 1982*).

<sup>214</sup> Ex. 858, Vol. 190, Tab 14, p. 8 (*Record of Decisions of the Canadian Blood Committee, March 22 - 23, 1983*).

<sup>215</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, p. 39750.*

<sup>216</sup> *Ibid, pp. 39744-39745.*

<sup>217</sup> Ex. 881, Vol. 213, Tab 13, p. 052369 (*Briefing book on the Canadian blood system, April 1991*).



consultation, or information provided to the Secretariat of the CBC through these two bodies, these two individuals that I have mentioned (Randy Klotz and Elaine Boily).<sup>218</sup>

154. Prior to 1983, the first analysis of the CRCS budget was undertaken by the Program and Finance Committee of the CBC, which contained the vestigial remnants of the Federal Provincial Budget and Program Review Committee. After 1983, this initial review was undertaken by the secretariat of the CBC. This process would entail numerous meetings with the CRCS, which often was required to provide further justification for its budget. This process normally took three to four months. Following this review, the secretariat would present the reduced budget to the CBC.

Once these budgets were reaching the Secretariat of the CBC, in return they were spending another three to four months in reviewing the material we had provided them with and, of course, consulting with us -- I will repeat -- on an almost daily basis, and various periodic actual meetings. Sitting down together and so on.

So the budget itself was an exercise that lasted almost a full year. And if it was not information that we were providing to the Secretariat, for wanting to request certain expenditures, it was them thereafter, contacting us to ask for additional justification for our requests.<sup>219</sup>

155. The Secretariat required detailed justifications for even relatively small expenditures. For example, in the 1985 budget submission the CRCS requested a part-time data entry clerk to deal with increasing work load volumes. The CRCS was required to provide an additional two page written justification for this position, even though it accounted for only a minuscule portion of the overall blood program budget.<sup>220</sup>

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<sup>218</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, p. 39746.*

<sup>219</sup> *Ibid, p. 39746.*

<sup>220</sup> *Ex. 957, Vol. 188, Tab C, pp. 278-279 (Toronto Centre Laboratory Staffing Justification - 1985 Budget Submission).*

*Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39760-39762.*



156. The CRCS was never allowed to present its budget to the CBC directly. It was always presented by the secretariat:

MR. MORIN: ...this is perhaps where the advantages, very large advantages were for the administration, my department if you want to, to have very good cordial exercise with the Secretariat at the CBC, being Randy and Elaine.

Knowing in advance that we would not be present to defend or to answer questions to representative -- provincial representatives or Canadian Blood Committee members, if you want to, it was certainly our advantage to make very, very sure that all information, as clear as possible would be provided to these people as they would be the ones presenting, answering questions, and defending our requests.

MS. EDWARDH: So I take it then, that they would then be your advocates really, before the CBC?

MR. MORIN: Exactly. It would have been so much easier. When you present your own things and then you provide your own answers, or you are there to listen or to hear why our request is not approved and so on, than to have to go through with third parties or having somebody else speak on our behalf.<sup>221</sup>

157. Despite the preliminary thorough review by the secretariat, the blood program budget would inevitably be reduced further by the CBC.<sup>222</sup>

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<sup>221</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39747 - 39748.*

<sup>222</sup> *Ex. 859, Vol. 191, Tab 4, pp. 178-179 (Record of Decisions of the Canadian Blood Committee Executive Committee, January 12, 1984); and*

*Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39760 - 39761.*



158. Between 1982-1986, the CBC never approved the entire budget at its first meeting in January.<sup>223</sup> CBC members frequently requested further justifications for items where it felt the secretariat had provided inadequate information.<sup>224</sup>

159. Since a number of CBC members had only limited budgetary approval authority, those members with such restrictions were required to consult their Treasury Boards before approving a budget in excess of their imposed limitations.<sup>225</sup> To minimize delay it was necessary for the CRCS to provide the CBC secretariat with information in formats suitable for all ten provincial Treasury Boards.<sup>226</sup>

160. The high turnover rate of CBC members dictated a learning curve to enable each member to become reasonably familiar with the blood program.<sup>227</sup> The education of CBC members caused severe delays in the timing of approval.<sup>228</sup> The prior experience of CBC members was in the approval process of hospital budgets, as the expectation of new members

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<sup>223</sup> *Ex. 858, Vol. 190, Tab 3, pp. 9-10 (Draft Record of Decisions of the Canadian Blood Committee, February 3-4, 1982);*

*Ibid, Tab 14, pp. 266-269 (Record of Decisions of the Canadian Blood Committee, March 22-23, 1983);*

*Ex. 859, Vol. 191, Tab 5, pp. 191-193 (Record of Decisions of meeting of the Canadian Blood Committee, January 30, 1984);*

*Ex. 860, Vol. 192, Tab 6, pp. 169-174 (Draft Record of Decisions of Meeting of the Canadian Blood Committee, January 15-16, 1985); and*

*Ex. 862, Vol. 194, Tab 4, pp. 105-112 (Draft Record of Decisions of the meeting of the Canadian Blood Committee, February 4-5, 1986).*

<sup>224</sup> *Ex. 862, Volume 194, Tab 4, p. 111, para. 43 (Draft Record of Decisions of the Canadian Blood Committee, February 4-5, 1986) Approval of the 1986 Blood Program Budget.*

<sup>225</sup> *Evidence of Mr. Hearn, former Chairman, Canadian Blood Committee, p. 35637; and*

*Evidence of Dr. Perrault, former National Director BTS, pp. 28781-28782.*

<sup>226</sup> *Ex. 736, Tab 50 (Letter from Mr. Weber to Dr. Leclerc-Chevalier, March 7, 1988).*

<sup>227</sup> *Evidence of Dr. Perrault, former Assistant National Director BTS, p. 28805-28808.*

<sup>228</sup> *Ex. 736, Tab 50 (Letter from Mr. Weber to Dr. Leclerc-Chevalier, March 7, 1986).*



was that the CRCS blood program budget would be cast the same way. A tendency to treat the blood program budget as a hospital budget further slowed down the process.<sup>229</sup> The lack of expertise in blood matters of the CBC secretariat and the absence of CRCS personnel at budget meetings required any clarifications to revert back to the CRCS through the secretariat.<sup>230</sup>

161. The delays inherent in this process meant that the full blood program budget was approved an average two to three months into the CRCS fiscal year.<sup>231</sup> Accordingly, one of the major recommendations of the Touche Ross Report was that the budget process be "streamlined".<sup>232</sup>

162. The CBC carefully scrutinized any proposed increases in staffing or any recurring expenses. Such increases resulted in permanent additions to the "A" base budget.<sup>233</sup> The CBC had an A inventory of all staff which had to be the same as the approved "A" and "B" budgets for the prior year.<sup>234</sup> Consequently CRCS was unable to make commitments to new staff or implement programs, until it had received formal approval by the CBC.<sup>235</sup> Since budget approval occurred two to three months into the fiscal year, and CRCS budgeted a full year for such costs, the blood program invariably had under-expended funds allotted to full time equivalents.<sup>236</sup> As a result of this problem, the CRCS had a surplus of funds at year end.<sup>237</sup>

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<sup>229</sup> *Ibid*, p. 2.

<sup>230</sup> *Ex. 860, Vol. 192, Tab 7 (The Canadian Red Cross Society Minutes of Budget Working Session with members of the Secretariat held on Tuesday, January 22, Wednesday, January 23, and Thursday, January 24, 1985).*

<sup>231</sup> *Ex. 957, Vol. 188, Tab F, p. 353 (Post-Audit Review of the National Blood Program of the Canadian Red Cross Society by Touche Ross, January, 1987).*

<sup>232</sup> *Ibid*, p. 353.

<sup>233</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39764-39765.*

<sup>234</sup> *Ibid*, pp. 39756-39758.

<sup>235</sup> *Ex. 957, Vol. 188, Tab F, p. 340 (Post-Audit Review of the National Blood Program of the Canadian Red Cross Society by Touche Ross, January, 1987).*

<sup>236</sup> *Ibid*, p. 340.



163. After approval, the CBC expected the CRCS to stay within the line by line amounts dictated by the approved budget. The CRCS had no discretion to hire full time personnel without first obtaining CBC authorization.<sup>238</sup> The CRCS had limited discretion within provincial equipment budgets. As CRCS budgets were approved on a provincial basis, the CRCS could not use funds allocated from one provinces' centre budget to another. Within a centre, the CRCS could use unexpended funds to purchase equipment that was vitally needed, eg. if a centre centrifuge became inoperative the purchase of another piece of equipment could be delayed and these funds used to replace the urgently needed centrifuge.<sup>239</sup> No justification for such action was required if it did not affect the bottom line of the provinces' equipment budget.

164. The CRCS had the ability to over-expend its budget on one time expenses of a limited magnitude.<sup>240</sup> Such expenses, however subsequently required full justification and approval by the CBC in order for the CRCS to be reimbursed. Any financing costs associated with the over-expenditure were not repaid by the CBC. All other major items required prior approval by the CBC. Depending on the size and significance of such requests, CBC members might first have to consult with their provincial Ministries and Treasury Boards.<sup>241</sup> Given the infrequency of CBC meetings, this process was cumbersome and induced delay.

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<sup>237</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30309-30311; and*

*Evidence of Mr. Claude Morin, pp. 40010-40011.*

<sup>238</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39823-39826.*

<sup>239</sup> *Ibid, pp. 39795-39796.*

<sup>240</sup> *Ibid.*

<sup>241</sup> *Evidence of Mr. Hearn, former Chair of CBC, pp. 35425-35427.*



d) The Vax Affair

165. While in theory the CRCS was the manager of the Canadian blood program, in practise, the CBC seriously circumscribed its ability to act in this capacity. Due to the absence of a national blood policy or written understanding between the CRCS and CBC, there were no guidelines as to the scope of authority of the CRCS in managing the blood program. Precedent was the only effective guideline the CRCS could follow. The dispute over the purchase of a 780 VAX computer by the CRCS, with consultation but without approval of the CBC, established a powerful precedent in the future management of the blood program by the CRCS.<sup>242</sup>

166. In early 1983, the CRCS Electronic Data Processing (EDP) Committee determined that the blood program urgently required a new mini computer. Consequently, in the CRCS 1984 blood program budget submission, an allowance was made for the purchase of a 780 VAX computer.<sup>243</sup> The CRCS viewed the need for such a computer for the blood program to be obvious and immediate.

167. Because of the urgency and possible delay in delivery, the CRCS sent a purchase order to Digital for this computer in September of 1983. Under the terms of the purchase order, the CRCS was entitled to cancel the order in January, 1984 without penalty.<sup>244</sup> The CBC was scheduled to approve the 1984 blood program budget in its January meeting.<sup>245</sup>

168. In December, 1983 the CBC hired an external computer consultant to evaluate the CRCS-proposed Blood Program Management Information System (hereinafter referred to as "BPMIS"), which included the VAX computer. The consultant's review of the systems

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<sup>242</sup> *Evidence of Mr. Klotz, CBC Panel, p. 36995; and*

*Evidence of Dr. Perrault, former National Director BTS, p. 30300.*

<sup>243</sup> *Ex. 736, Tab 29 (Summary of Decision Making Process for VAX computer, March 13, 1984).*

<sup>244</sup> *Ibid.*

<sup>245</sup> *Ex. 736, Tab 30 (VAX Purchase Order Decision, by Dr. Perrault, March 14, 1984).*



department was extremely favourable. He indicated his confidence in the CRCS Systems Department and noted the lack of development of computer systems in the blood program.<sup>246</sup>

169. The CRCS fully expected the CBC to approve this item:

We never thought by making a decision such as this, and developing thereafter much better management controls in the blood program, that the governments would hesitate to refund the Red Cross for this.

So this is basically why we went with clear conscience that this would be such an asset to all governments, that it is a given.<sup>247</sup>

170. In January, when the CBC reviewed the blood program budget it moved the VAX computer from the "A" budget into the "B" budget. The CBC then approved the "A" budget, but refused to approve the "B" budget.<sup>248</sup>

171. In February, the "B" budget had still not been approved. The CRCS contacted the CBC requesting a decision on the VAX computer as the cancellation date was approaching.<sup>249</sup> Upon discovery that the purchase order had been made for the VAX computer, the CBC requested the CRCS to explain its conduct.<sup>250</sup>

172. At the March 22, 1984 meeting between the Executive Committee of the CBC and Senior CRCS staff, the CRCS was informed that putting in a purchase order for the VAX without formal CBC approval was a serious mistake. The CBC informed the CRCS that even

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<sup>246</sup> Ex. 736, Tab 24 (*Letter from Mr. Frederickson to Dr. Leclerc-Chevalier, December 5, 1983*).

<sup>247</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 39769-39770.*

<sup>248</sup> Ex. 736, Tab 27, p. 10 (*Record of Decisions of meeting of the Canadian Blood Committee, January 30, 1984*).

<sup>249</sup> Ex. 736, Tab 30, p. 4615A, (*Telex from Mr. Weber to Dr. Leclerc-Chevalier, February 23, 1984*).

<sup>250</sup> *Ibid.*



though the CBC might feel that the VAX was needed "in principle", funds might still not be available for such an undertaking.<sup>251</sup>

173. The CBC refused to make a decision on the purchase of the VAX computer and the CRCS was forced to carry the cost of this computer. When the CBC ultimately recognized its necessity in 1985 and agreed to provide funds for it, the CRCS was still responsible to absorb the financing costs for 1984.<sup>252</sup>

174. On May 1, 1984 at a meeting between the Executive of the CBC and Senior CRCS officials, the CRCS was reminded that any decision having an economic impact on the provinces and territories must be taken only after consultation with the CBC.<sup>253</sup>

175. This message was reiterated at the August 22, 1984 meeting between the Executive Committee of the CBC and the officials, members and staff of the CRCS. The CRCS was reminded that consultation with the CBC before making decisions which financially impacted on the provinces was a pre-requisite.<sup>254</sup>

176. Again, in 1988 the Vice-Chairman of the CBC reiterated that the issue of the VAX computer was an irritant to the CBC during a meeting with George Weber, the Secretary General of the CRCS.<sup>255</sup>

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<sup>251</sup> *Ex. 736, Tab 31 (Record of Meeting held at Queen's Park on March 22, 1984 between the Canadian Red Cross Society and the Executive Committee of the CBC).*

<sup>252</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, pp. 40005-40006.*

<sup>253</sup> *Ex. 736, Tab 33, p. 9 (Draft Record of Decisions at the meeting of the Canadian Blood Committee, May 4, 1984).*

<sup>254</sup> *Ex. 859, Vol. 191, Tab 11, p. 327 (Summary of Discussions of meeting of the Executive Committee of the CBC, August 22, 1984).*

<sup>255</sup> *Ex. 737, Tab 15 (Memo to file by George Weber, November 3, 1988).*



177. Following the VAX incident, the CRCS was cognizant that all decisions having a financial impact on the funding governments required prior approval by the CBC.<sup>256</sup> Such approval was required for all decisions: there were no exceptions for decisions concerning the safety of the blood program.<sup>257</sup>

178. Although the language contained in the minutes of these meetings seemed to contemplate 'consultation', members of the CBC testified that it would prevent the CRCS from taking any course of action contrary to the will of the CBC. In other words, the CBC required its consent to any such expenditures:

THE COMMISSIONER: But can I ask you this question, does "consult" in your terminology, in your vocabulary, mean anything more than inform us? Consult with us, does that contemplate more than simply informing us?

MR. HEARN: I think in the context of a major issue it means more than informing us.

THE COMMISSIONER: Therefore, seek our consent?

MR. HEARN: Well, it is reasonable principle. If you are going to ask me to pay, then seek my consent.<sup>258</sup>

CRCS officials also testified that 'consultation' actually meant approval.<sup>259</sup>

179. Following 'vaxination', CRCS managed the blood program with the knowledge that major funding thrusts could not be undertaken without the approval of the CBC.

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<sup>256</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30300-30301; and Evidence of Mr. George Weber, former Secretary General, p. 40477.*

<sup>257</sup> *Evidence of Mr. Randall Klotz, CBC Panel, p. 36848.*

<sup>258</sup> *Evidence of Mr. Hearn, former Chairman, Canadian Blood Committee, pp. 35628-35629.*

<sup>259</sup> *Evidence of Mr. Claude Morin, former National Administrator CRC BTS, p. 39770.*



e) CBC Policy Formation - The Autologous Program

180. In the absence of a national blood policy, the CBC rendered decisions in an ad hoc manner. The issue of autologous donations illustrates how policy was delivered and administered in the blood system wherein concerns over public perception and costs became the dominant factors in policy formulation by the CBC.

181. The historical role of the CRCS entailed recruiting a sufficient number and quality of donors to meet blood product needs in Canada. It was further tasked with the collection, processing, and distribution of the blood received from these donors.<sup>260</sup> Until the mid 1980's, the CRCS undertook autologous donations only in rare cases where the recipient could not benefit from a normal, homologous donation, ie. the donor had a very rare blood type.<sup>261</sup>

182. The adoption of a national autologous program was not readily compatible with the ongoing procedures of the CRCS. Initially, the BTS did not have the appropriate infrastructure to offer a wide scale autologous program.

183. The CRCS collection centres were equipped and staffed to manage the traditional, healthy, volunteer donors who provided blood to the general Canadian population. An autologous donation program was a substantial departure from the normal CRCS donor criteria as some candidates for autologous transfusion might not be in a healthy state. Accordingly, various precautions were required, which were not necessary for a healthy volunteer donor. Some candidates for autologous transfusion were cardiac patients. There was a concern that such a patient could suffer a vascular coronary or cerebral compromise during the donation process. CRCS collection centres were not set up to perform resuscitation in the event of such an occurrence.<sup>262</sup>

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<sup>260</sup> *Ex. 736, Tab 7, (CRCS Commentary CBC Terms of Reference, April, 1982).*

<sup>261</sup> *Evidence of Dr. Rock, pp. 23398-24000.*

<sup>262</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 28096-28097.*



184. A separate system was necessary to ensure the systematic flow and proper organization of blood. In addition, there was a concern that it may not always be convenient for physicians to refer their patients to the CRCS, particularly in large urban areas where the centre was located a considerable distance away from the hospital where the surgery was to be performed or where the patient resided.<sup>263</sup>

185. All of the above considerations had to be evaluated and addressed before the CRCS could launch a nationwide autologous program.<sup>264</sup>

186. The CRCS advised the CBC of the growing pressure applied by the medical community to make exceptions to the policy on autologous transfusions in light of AIDS. In a position paper dated September 30, 1985, the CRCS informed the CBC that, from a safety perspective, autologous blood donation was undoubtedly the safest blood transfusion one could receive. It recommended a change in policy to accommodate autologous donations and advised that such a change would involve potential cost increases. It further advised that it may give rise to legal and regulatory issues as well as a consideration of the new relationships which may be established between the BTS and the hospitals. The CRCS recommended that were these types of donations to proceed, they be carried out at the hospital blood bank or the CRCS BTS. As governments might have to contend with requests from agencies to establish autologous blood banks, a policy would be required in this regard.<sup>265</sup>

187. At the November 4, 1985 CBC Advisory Sub-Committee meeting, the issue of autologous donations was discussed. Dr. Ingraham, the chair of the sub-committee, and a CBC representative, stated that autologous transfusions should not be part of the medicare system as the governments were already funding the national blood program administered by the

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<sup>263</sup> *Ibid.*

<sup>264</sup> *Ibid.*

<sup>265</sup> *Ex. 861, Vol. 193, Tab 3, pp. 270-272 (CRCS Position Paper on Autologous/Designated Blood Donations by Dr. Perrault, September 30, 1985).*



CRCS.<sup>266</sup> Dr. Bowman, of the Winnipeg Rh Institute, characterized the incorporation of autologous donations into CRCS activities as a "nightmare" and expressed concern that performing even a small number of such donations would create a dangerous precedent. Dr. Perrault suggested that an attempt be made to quantify the extent of the problem in each province suggested that a strict protocol with the proper set of controls be prepared. The Advisory Sub-Committee agreed with Dr. Perrault's recommendation.<sup>267</sup>

188. A presentation was made by the CRCS Ad Hoc Committee on Autologous and Directed Donations to the CRCS medical directors' on March 19, 1986. Dr. Blajchman, who presented the paper, opined that autologous donations were a necessary option that should be provided by the BTS. The committee pointed out, *inter alia*, that:

1. Autologous blood transfusion was undoubtedly the safest transfusion one could receive;
2. Donors, when they gave an autologous donation might become volunteer altruistic blood donors;
3. It was an opportunity to educate donors and recipients on this blood program and its benefits; and
4. It provided psychological relief for the patient and physician;

The medical directors agreed that the autologous blood transfusion option should be taken to the BTS Advisory Committee.<sup>268</sup>

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<sup>266</sup> *Ibid*, p. 259 (*Draft Record of Decisions of the Seventh Meeting of the Advisory Sub-Committee to the CBC, November 4, 1985*).

<sup>267</sup> *Ibid*, p. 259.

<sup>268</sup> Ex. 643, Vol. 40, Tab 25, p. 66434 (*Position Paper on Autologous and Directed Donations, by the Ad Hoc Committee on Autologous and Directed Donations, February 3, 1986*); and



189. On April 18, 1986 the BTS Advisory Committee passed a motion calling for a pilot project on autologous blood donation in order to assess the logical and financial implications of such a program. Dr. Leclerc-Chevalier explained that the CBC had not yet adopted a position on autologous donations and authorized the pilot project to collect data.<sup>269</sup>

190. Dr. Perrault informed Dr. Leclerc-Chevalier that the pilot projects were ready to be implemented in Toronto and Ottawa in early 1987. Dr. Leclerc-Chevalier informed the CRCS that these projects were to be conducted within the existing budget of the CRCS blood program.<sup>270</sup>

191. The issue of autologous donations was revisited at a joint meeting between the executives of the CBC and the CRCS on April 24, 1987. Dr. Perrault explained that the need to develop data had prompted the implementation of the pilot projects. Dr. Sullivan of the CBC questioned the mixed message that was being sent by the CRCS in this pilot study. He expressed concern that making autologous donations available would raise the issue of the safety of the general blood supply. Dr. Whittemore, on behalf of the CRCS, replied that while the issue was not the safety of the national blood supply, autologous blood could be provided to any patient as the "best possible" blood.<sup>271</sup>

192. The CRCS pilot project was discussed at the April 29-30, 1987 meeting of the CBC. A number of its members believed that it was inconsistent to simultaneously take the position that the safety and quality of the blood supply was satisfactory, while providing for autologous transfusions. Although it was suggested that the CBC approach NAC AIDS or its advisory committee for advice on this matter, it does not appear to have done so. Instead, contrary to the expert advice of its sub-committee on the subject, and notwithstanding the pilot

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*Ibid*, pp. 66352-66372 (*Minutes of Medical Directors Meeting, March 19-21, 1986*).

<sup>269</sup> Ex. 644, Vol. 41, Tab 22, p. 70163 (*Minutes of the National BTS Advisory Committee, April 18, 1986*).

<sup>270</sup> Ex. 648, Vol. 45, Tab 26 (*Letter from Dr. Leclerc-Chevalier to Dr. Davey, March 5, 1987*).

<sup>271</sup> Ex. 864, Vol. 196, Tab 3, p. 29 (*Joint Canadian Blood Committee/Canadian Red Cross Society Executive Committee Meeting, April 24, 1987*).



projects had been approved by the CRCS medical directors and the BTS Advisory Committee, it passed a motion directing the CRCS to phase out the pilot projects it had implemented. The CBC informed the CRCS that there would be no expansion of autologous donations across Canada.<sup>272</sup>

193. On May 11, 1987, Dr. Leclerc-Chevalier informed the CRCS that there was no medical reason why the CRCS should expand its autologous transfusion service and stated that the pilot projects were to be phased out as soon as possible.<sup>273</sup>

194. The CRCS was disappointed at this response. It questioned the position that there were no medical reasons to expand the autologous transfusion service when it was commonly believed that autologous transfusion provided an additional element of safety in blood transfusion.<sup>274</sup> The CBC reconsidered its decision at its meeting on September 1-2, 1987. At this meeting the members were informed that the Canadian Medical Association passed a motion encouraging support for a CRCS autologous blood transfusion service.<sup>275</sup> Members of the CBC expressed concern that its decision not to allow autologous donation might be overturned, thus damaging the credibility of the CBC. Five months after its rejection of the national autologous donation program, the CBC requested further information on it from the CRCS, and recommendations from its Advisory Sub-Committee.<sup>276</sup>

195. The CBC Advisory Sub-Committee considered this matter at its October 14, 1987 meeting. It unanimously recommended that the CRCS be supported and encouraged in its efforts to establish a national autologous blood donation service for elective surgery accessible to all

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<sup>272</sup> *Ibid*, pp. 82-84 (*Record of Decisions of the Meeting of the Canadian Blood Committee, April 29-30, 1987*).

<sup>273</sup> *Ex. 737, Tab 2 (Letter from Dr. Leclerc-Chevalier to Dr. Davey, May 11, 1987)*.

<sup>274</sup> *Evidence of Dr. Davey, former Assistant National Director BTS, p. 30686*.

<sup>275</sup> *Ex. 865, Vol. 197, Tab 1, p. 10 (Record of Decisions of the Meeting of the Canadian Blood Committee, September 1-2, 1987)*.

<sup>276</sup> *Ibid*, p. 12.



Canadians and administered under the authority of, and according to, CRCS standards.<sup>277</sup> When this decision was communicated to the CBC at its October 16, 1987 meeting, Dr. Sullivan, the chair of the Advisory Sub-Committee, informed the CBC that the issue received little discussion at the Sub-Committee's meeting. He suggested that the CBC acquiesce with the expanded service without providing positive support. This would constitute an interim position before developing a longer term policy. Mr. Dreezer suggested that a letter to the CRCS outlining the CBC's position be prepared by the secretariat and forwarded to all members of the committee for their approval. Some members expressed the desire to consult with their political authorities in their province.<sup>278</sup>

196. Following this meeting the CBC requested the CRCS to develop a protocol on the practise of autologous transfusions to be applied uniformly in all centres. The protocol was considered by members of the CBC's Advisory Sub-Committee and considered by the CBC at its December 8, 1987 meeting.<sup>279</sup>

197. After consideration, the committee decided to allow the CRCS to expand its current autologous transfusion program to include elective surgery, provided that:

- a. the programme be implemented without additional cost to the blood programme;
- b. the programme be implemented in line with the protocol developed by the Red Cross and amended by the CBC;
- c. quarterly operation and financial reports pertaining to the programme be provided to the CBC; and
- d. no publicity be initiated by the Red Cross on the expansion of the programme.<sup>280</sup>

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<sup>277</sup> *Ibid.* Tab 2, p. 168 (*Record of Decisions of the Tenth Meeting of the Advisory Sub-Committee to the CBC, October 14, 1987*).

<sup>278</sup> *Ibid.* Tab 3, pp. 192-196 (*Record of Decisions of the Meeting of the Canadian Blood Committee October 16, 1987*).

<sup>279</sup> *Ibid.* Tab 6, p. 301 (*Meeting of the CBC, December 8, 1987*).

<sup>280</sup> *Ibid.* pp. 301-302.



198. Dr. Perrault was of the opinion that these restrictions severely hampered the success of this program:

Well, the "don't spend any money, don't promote it" sure did not allow a very strong launch.<sup>281</sup>

199. The limitation on publicity had a twofold effect: public confidence in the blood system was not undermined; and the absence of publicity ensured the program would not be widely used. Consequently little additional cost would be incurred. These restrictions succeeded in limiting the success of the program.

200. On March 28, 1989, Dr. Peter Glynn, the Vice-Chair of the CBC, noted that since the beginning of 1988 only 1,250 procedures had been performed by the CRCS. He recognized that while wider publicity of the availability of this service might well increase demand, it had been discouraged by the CBC in view of the associated higher costs of operating an autologous program.<sup>282</sup>

201. The publicity condition was strictly enforced by the CBC. Following a complaint from the Autologous Blood Bank (a private blood bank in Montreal) that the CRCS was competing with it for autologous donations, the CBC wrote to the CRCS on June 23, 1988 accusing it of publicizing its autologous program in violation of the "no publicity" principle laid down by the CBC prior to its authorization.<sup>283</sup>

202. The CRCS was perplexed by the CBC's attitude. The publicity to which the CBC referred was a brochure at "Salon de Santé", a May 1989 health fair for hospital personnel in Quebec.<sup>284</sup> In response to numerous questions from Quebec surgeons, the brochure has been

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<sup>281</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 30689-30690.*

<sup>282</sup> *Ex. 879, Vol. 211, Tab 60 (Paper on autologous donations by Dr. Peter Glynn, March 28, 1989).*

<sup>283</sup> *Ex. 867, Vol. 199, Tab 8, p. 256 (Letter from Dr. Perrault to Dr. Hauser, June 28, 1989).*

<sup>284</sup> *Ibid, pp. 261-264 (Letter from Dr. Perrault to Dr. Hauser, July 10, 1989).*



designed in 1987 during the autologous donation pilot project. The CRCS disagreed that responding to questions posed by practitioners to enable them to understand the program, constituted publicity. They questioned whether the "no publicity" condition was instituted by the CBC to protect private blood banks from unpaid competition. The CRCS expressed concern that by instructing the CRCS not to compete with a private blood bank it was, in fact, encouraging the violation of one of the four ministerial principles regarding the "gratuity of blood products".<sup>285</sup> The CRCS reiterated that the policy restrictions on the autologous program were seriously hampering its development. It was concerned that members of the public might conceive that the failure to share information on autologous transfusions equally with all hospitals and potential recipients was a violation of the trust CRCS had with its clients.<sup>286</sup>

203. At its October 4-5, 1989 CBC meeting, the CBC reassessed its policy on autologous donations and removed the limitation on publicity. It did not, however, allocate any funds for the purpose of promoting the program.<sup>287</sup>

204. This issue was referred to the Advisory Sub-Committee of the CBC for consideration during its November 29, 1989 meeting. The Canadian Haematology Society made recommendations that the program should be supported and expanded and stated that practitioners and hospitals needed to be provided with information about the availability of the autologous donation program in order to make better use of it. The CRCS noted that there would be a cost associated with any expansion of the program.<sup>288</sup>

205. At the December 13-14, 1989 meeting of the CBC, autologous donations was again discussed. Dr. Perrault, who circulated a position paper at the meeting, stated that an

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<sup>285</sup> *Ibid.*, pp. 256-257 (Letter from Dr. Perrault to Dr. Hauser, June 28, 1989).

<sup>286</sup> *Ibid.*, p. 259.

<sup>287</sup> *Ibid.*, Tab 8, p. 217 (Record of Decisions of the Meeting of the Canadian Blood Committee, October 4-5, 1989).

<sup>288</sup> Ex. 868, Vol. 200, Tab 2, p. 29 (Record of Decisions of the Twelfth Meeting of the Advisory Sub-Committee to the CBC, November 29, 1989).



increase in autologous blood donations would have a financial impact on the cost of the Canadian blood program. He stressed the importance of education and promotion at the physician, hospital and patient levels. He reiterated concerns regarding standardized donor criteria and accessibility of donor sites. He further noted that the lack of additional resources allocated to the autologous blood program had been a limiting factor in the growth of the program.<sup>289</sup>

206. Notwithstanding these facts, the CBC refused to adequately fund this program. The official record of this meeting states:

Members reinforced the prudence of their October 4-5, 1989 decision. They had removed only the publicity limitation from the December 8, 1987 decision. The three other conditions...continued in effect. The CRCS should be informed that the CBC's lifting its ban on publicity does not require the Society to publicize the program. The program should continue to be run without additional cost to the approved Blood program budget.<sup>290</sup>

207. The CBC developed its policy on autologous donations based on public perception and cost. It did not want the public to gain the impression that, by offering autologous donations it was admitting there was a safety concern with the blood supply. Nor did the CBC want the autologous program to impact financially on the blood program. These considerations, rather than scientific or medical concerns, drove the CBC's policy. Because of the publicity prohibition, many persons who may have benefitted from autologous donations during the period between 1987-1989 were unaware of this service. Transfusions were also limited by the fact that the CRCS was allocated no additional resources to perform these procedures, despite the CBC's awareness that there was an additional cost associated with this procedure. As with many of the CBC's ad hoc policies, the effect of its autologous policy was more of a brake than a steering wheel.

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<sup>289</sup> *Ibid*, Tab 3, pp. 70-73 (Position Paper on Autologous Blood Program by Dr. Perrault, November 29, 1989).

<sup>290</sup> *Ibid*, Tab 3, p. 41 (Record of Decisions of the Meeting of the CBC, December 13-14, 1989).



f) Conclusion

208. The absence of a national blood policy to guide the CBC in its interactions with the CRCS resulted in decisions rendered by the CBC in an ad hoc manner. As a consequence of the high-turnover rate of CBC members, its lack of technical resources, its limited authority, the fact that decisions required the agreement of all CBC members, and the fact that none of its members devoted their full time toward policy development in the blood programme, issues could not be resolved expeditiously nor could policy be made without the external validation of another bureaucratic layer of approval. For example, the absence of a defined policy on safety required the CRCS to obtain approval and a commitment from the CBC to implement testing which, in turn, required the CBC to obtain unanimous approval from their ten respective Ministries of Health.<sup>291</sup> Although the CBC was mandated by the federal and provincial governments to direct the blood system, it lacked the authority, resources and accountability to do so.<sup>292</sup>

209. The CRCS was not invited to CBC meetings nor did it receive copies of these meetings. On occasion it was called upon to make presentations to the CBC about funding issues but was excluded from the discussion by the CBC members.<sup>293</sup> The CRCS had no formal recourse from adverse decisions by the CBC.<sup>294</sup> Its only route was to appeal directly to the Ministers or the people of Canada; however, Ministers were advised on blood matters by the

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<sup>291</sup> Considering the debate and rigorous scrutiny this funding decision by the CBC entailed, it is anomalous that "emergency funds" were released for the subsidization of certain provincial fractionators without recourse to the ten provincial treasury boards as discussed in Part I.

<sup>292</sup> Ex. 736, Tab 7, p. 29 (Commentary by the Canadian Red Cross Society on CBC Draft Terms of Reference, April 12, 1982);

Ex. 737, Tab 23, p. 1 (The Management of the Canadian Blood System: A Discussion Paper of the Ad Hoc Working Group, August 25, 1989); and

Evidence of Dr. Denise Leclerc-Chevalier, former Executive Director, Canadian Blood Committee, p. 37134.

<sup>293</sup> Ex. 861, Vol. 193, Tab 1, pp. 13-18 (Draft Record of Decisions of the Meeting of the CBC, June 4-5, 1985).

<sup>294</sup> Ex. 736, Tab 7 (CRCS Commentary on CBC draft Terms of Reference, April 1982).



same representatives who sat on the CBC. The CRCS learned from experience that Ministers of Health and the CBC reacted strongly against CRCS appeals to the public.<sup>295</sup> To preserve ongoing relations, the CRCS rarely resorted to such appeals.<sup>296</sup>

210. The mandate of the CBC to be an effective director of the Canadian blood system was further complicated by the fact that this same body which established policies for the blood system was also responsible to the provinces for ensuring that the system operated as economically as possible. Moreover, members advanced provincial priorities in a system that should have been designed to benefit the nation as a whole.

211. It was necessary for the federal and provincial governments to establish a national policy for the blood system. The CBC failed as the instrument for this purpose. The CRCS, in 1982, accurately prophesied things to come:

Some countries have introduced legislation for blood transfusion. The United States has implemented a blood policy to provide various parties and participants within their blood system with time and opportunity to reconcile differences and to prepare the environment for national legislation and to prepare a basis for national legislation, while proceeding with Federal legislation at the same time.

The Canadian Red Cross Society recognizes the need for a Canadian blood policy and will support any effort of government to formulate such policy through consensus among Provincial and Federal governments, among user and supplier groups, and between government, user and supplier groups.

Whereas the need for Canadian blood policy in the absence of Federal legislation is easily recognizable, its current purpose, to provide a basis for management of the blood programme through a Federal/Provincial Committee, may be of limited benefit to the blood programme and the public. It is the position of the

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<sup>295</sup> Ex. 860, Vol. 192, Tab 10, pp. 249, 268-269 (*Record of Decisions of Meeting of the Executive Committee to the CBC, April 17, 1985*);

*For example, in 1985 the CBC warned the CRCS and members of NAC AIDS, that it took a dim view of announcements that AIDS testing was going to occur that summer. Such announcements were to wait until approval of the programme by the CBC.*

<sup>296</sup> Ex. 873, Vol. 205, Tab 10, p. 79 (*Excerpt of transcript of conference of Provincial Ministers, September 30 to October 1, 1981, St. John's, Newfoundland*).

*In fact, the CBC was formed partly as a result of the Ministers' requirement to deal with "the political antics of the Red Cross".*



Canadian Red Cross Society, that the blood programme would be better served with Federal legislation, such legislation being more suitable to support a national programme and more impartial than policy. Should this not be the ultimate objective of policy formulation, the Canadian Red Cross Society would find it difficult to reconcile its fundamental corporate principles, the principles governing its blood programme and its commitment to international resolutions and recommendations, with such policy, *as primarily dictated by political and economical circumstances of the day*. Moreover, in situations where the Canadian Red Cross Society may wish to seek redress, it could not use the legal route but would have to resort to political solutions.<sup>297</sup> [Emphasis added]

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<sup>297</sup> Ex. 736, Tab 7 pp. 31-32 (April 12, 1982, Canadian Blood Committee Draft Terms of Reference Commentary by the Canadian Red Cross Society).



C. CANADIAN SELF-SUFFICIENCY

1) Introduction

212. One of the cornerstones of the Canadian blood system and entrenched in the Ministerial principles was the belief that Canada should be self-sufficient in blood and blood products:

PRINCIPAL #2

TO ENSURE SELF-SUFFICIENCY OF BLOOD PRODUCTS BY REDUCING  
CANADA'S DEPENDENCE ON FOREIGN SOURCES OF BLOOD  
PRODUCTS SUPPLY, PARTICULARLY THOSE THAT RELY ON  
PURCHASED PLASMA FOR RAW MATERIAL.<sup>298</sup>

213. Self-sufficiency can be interpreted in three ways: sufficient Canadian plasma to meet Canada's demand, domestic fractionation capability, or both. Both objectives were recognized as worthy goals. The CRCS supported both aspects, but considered self-sufficiency in collections to be paramount as it believed that plasma collected from Canadian volunteers was safer than commercially purchased plasma from U.S. paid donors.<sup>299</sup> For this reason the CRCS sought to maximize product from Canadian source plasma.

214. Unlike the CRCS, the provinces' strategy for self-sufficiency was focused almost entirely on manufacturing. The proposal by the CRCS for a single fractionation plant was dismissed in favour of utilizing existing capacity at Connaught Laboratories (CLL). The CRCS was forced by the provinces, and in particular Ontario, to use CLL as a supplier of Anti-Hemophiliac Factor (hereinafter referred to as "AHF") despite grave concerns about CLL's competence to manufacture a sufficient quantity and quality of concentrates. The CRCS and hemophilia groups warned the provincial representatives about CLL's antiquated facilities and

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<sup>298</sup> Ex. 736, Vol. 1, Tab 7, p. 103 (Second ministerial principle as cited in the commentary by the CRCS of the CBC Draft Terms of Reference, April 12, 1982).

<sup>299</sup> Evidence of Dr. Perrault, former National Director BTS, p. 26175.



lack of expertise. However, these warnings were consistently ignored in a series of government decisions that displayed an alarming preference for political expediency which ultimately compromised the quantity and quality of blood products supplied to Canadian hemophiliacs. The strategy of the CRCS for Canadian self-sufficiency in plasma is detailed below, in contrast to the provincial strategy.

2) Self-Sufficiency in Plasma Collections - The CRCS Strategy

215. Throughout the 1980's, the CRCS attempted to pursue the goal of self-sufficiency by promoting the collection of plasma from volunteer Canadian donors to satisfy Canada albumin and Factor VIII requirements.<sup>300</sup> By 1978, the CRCS produced sufficient quantities of plasma to meet domestic requirements for albumin; however, it was unable to collect sufficient plasma to satisfy the growing demand for Factor VIII. There were several impediments to achieving self-sufficiency in plasma collections, all of which were beyond the control of the CRCS. These included: funding restrictions placed on the CRCS by the CBC; plasma wasted by CLL in its failed attempts to produce a suitable Factor VIII product; reduced yields from heat-treated product; and shortages flowing from product withdrawals and recalls. Details concerning these various factors are set out below.

a) **Lack of Funding for Self-Sufficiency**

216. While the provinces claimed to support the principle of plasma collection self-sufficiency, they did not adequately fund the collection efforts of the CRCS to meet this objective:

MR. STEVENSON: Yes. You seem to feel very strongly about this (increasing plasmapheresis collections).

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<sup>300</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 26289-26291.*



DR. PERRAULT: Well, I thought the Ministers did also, but what I found as we moved along, they approved the principle, but as I heard on a number of occasions during discussions, "not at any price". And this was an uphill battle.<sup>301</sup>

217. By 1978, the CRCS reached its goal of maximizing component production and began to focus its efforts on plasmapheresis collections.<sup>302</sup> The importance of plasmapheresis, as opposed to whole blood collection, was that a single donor could donate many more times during a year.<sup>303</sup> This increase would entail less reliance on non-volunteer, foreign sources of plasma. Further, to increase whole blood collections just for the plasma would result in wasted components. The provinces thwarted this initiative by failing to adequately fund the program.

218. While plasmapheresis collections were more expensive than supplementary purchases, the CRCS believed the additional costs were justified. Its funders did not. When the Chapin Key Committee studied the issue of plasma self-sufficiency in its November, 1980 report, it concluded that supplementary purchases were more economical than increasing collections:

We have been advised that the volume of plasma required to provide self-sufficiency in Factor VIII at a standard of 35,000 Anti-Hemophilic Factor (AHF) units/hemophiliac (75% AHF concentrate and 25% cryo mix) is 244,878 litres...at this level of collections, significant surpluses of all other products would be created. In the view of this Committee, to increase collections to provide this level of plasma for Factor VIII only would not be reasonable, economic or practical. The cost of increasing collections to provide this level of plasma would be between \$10.1 million and \$15 million per year depending on the collection alternatives, whereas the cost of purchasing the AHF concentrate to make up a requirement beyond what is produced with current volumes of plasma within Canada is \$1.5 million...<sup>304</sup>

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<sup>301</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 26336.*

<sup>302</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 26312.*

<sup>303</sup> *Until 1989 whole blood collections were limited to four per year.*

*Ex. 655, CRCS Vol. 52, Tab 4 (National Blood Services Committee, Minutes of Meeting, March 31, 1989).*

<sup>304</sup> *Ex. 871, Vol. 203, Tab 10, p. 154 (Report to the Provincial Ministers of Health, November, 1980 by the 1980 Inter-Provincial Ad Hoc Committee on Plasma Fractionation).*



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The Chapin Key Committee also recommended that the proposed Canadian Authority on Blood Policy (which became the "CBC") be given the authority to determine the lead product with respect to self-sufficiency in plasma collection.<sup>305</sup>

219. On March 2, 1981, Dr. Perrault wrote to Dr. Chapin Key, Deputy Minister of Health for British Columbia and the Chair of the Provincial Ministers of Health Ad Hoc Committee on Fractionation:

One topic that I gave further thought to following our meeting on February 23, was the issue of plasmapheresis to augment the production levels of the National Blood Transfusion Service of the Canadian Red Cross Society. As you are well aware, we have studied this matter extensively over the last two years and our reasons for not getting into this field sooner is simply a matter of resources. As you know, we had requested a beginning in this project two years ago but were not given the fiscal resources to do so. However, we did complete the donor trials as far as safety and donor acceptability and these proved highly successful. We have reported these findings to the Federal-Provincial Budget Review Committee and are once more submitting a proposal for 1981.<sup>306</sup>

220. Throughout the early 1980's, the CRCS unsuccessfully pushed for self-sufficiency in all of the major blood fractions. On December 16, 1982, Mr. D.C. McNaught, special advisor to the CBC, wrote to Dr. Perrault with his concerns that the CRCS proposed plasma collection was going to result in an over supply of albumin. He suggested that the CRCS reduce its proposed plasmapheresis program from 24,000 procedures to 12,000 procedures.<sup>307</sup>

221. The CRCS responded by informing Mr. McNaught that Canadian demand for albumin was likely to increase, and reminded him that the plasmapheresis program was not designed solely to ensure albumin supplies but also to move Canada towards self-sufficiency in Factor VIII from Canadian source plasma. Dr. Perrault informed Mr. McNaught:

Another issue which must be considered in relation to albumin supply is the provision of Factor VIII concentrate. If the goal of attaining self-sufficiency in

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<sup>305</sup> *Ibid* at p. 153.

<sup>306</sup> Ex. 612, CRCS Vol. 9, Tab 29 (Letter from Dr. Roger Perrault to Dr. Chapin Key, March 2, 1981).

<sup>307</sup> Ex. 736, Vol. 1, Tab 15 (Letter from Mr. D.C. McNaught to Dr. R.A. Perrault, December 16, 1982).



Factor VIII concentrate production is pursued, there will be, in the short term, an excess of albumin available over requirements. One could consider that levels of albumin utilization in Canada be allowed to increase from the current 128 kg/10<sup>6</sup> population to the accepted levels in similar countries of 150 - 200 kg/10<sup>6</sup> population. This increase in utilization could be accommodated by the level of plasma production that will support self-sufficiency in Factor VIII concentrate. Any short term surplus of albumin over Canadian requirements could perhaps be distributed to other national transfusion services on a cost recovery basis.<sup>308</sup>

222. The CBC appeared more swayed by the accounting figures than the goal of self-sufficiency. They consistently denied the recommendations of the CRCS regarding the number of plasmapheresis procedures as is reflected in the CBC March 1983 minutes:

The major modification in the proposed Red Cross budget is the reduction of the pheresis program by 50%; the recommended level is 15,800 procedures (for cells and plasma), as compared to the 28,000 level recommended by the Red Cross. These details are presented in Schedule 4. This level, if adopted, will delay progress towards self-sufficiency, particularly for Factor VIII. A supplementary purchase of approximately 22 million AHF units is required again for 1983. The pheresis system will not operate at optimal efficiency; however, the reduced activity will not add to the growing inventory of albumin.<sup>309</sup>

223. The CBC's rejection of repeated CRCS requests for increased funding for plasmapheresis collections documented its preference for short term economy over long term security. The disparity between funding requests and approvals is strikingly evident:

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<sup>308</sup> *Ex. 736, Tab 17 (Letter from Dr. R.A. Perrault to Mr. D. McNaught, January 24, 1983).*

<sup>309</sup> *Ex. 858, Vol. 190, Tab 14, p. 267 (Record of Decisions of the Canadian Blood Committee Meeting, March 22 to 23, 1983).*



<u>Year</u>	<u>Number of Plasmapheresis Collections Requested by CRCS</u>	<u>Number of Plasmapheresis Collections Approved by Provinces/CBC</u>
1982	18,000	13,700
1983	24,000	12,000
1984	24,000	12,000 (additional 4,000 subsequently approved)
1985	24,000	24,000

224. In 1981, the provincial Ministers of Health set an objective for future plasma collections in Canada. A target of 200,000 litres per year was to be achieved by 1985.<sup>310</sup> This required an additional 76,000 plasmapheresis collections per year above its 1981 collections. Such a goal could only be achieved in stages with yearly increases in collections. Notwithstanding, a review of the approved CRCS budgetary figures for plasmapheresis collections (summarized in the above paragraph) demonstrates that the CBC was not committed to achieving this goal.

225. It was only in 1985 when the CRCS reiterated its proposal for 24,000 plasmapheresis collections,<sup>311</sup> that the CBC approved the full level of plasmapheresis collections requested.<sup>312</sup> Despite this authorization, it is important to note that 24,000 collections generated only 155,925 litres of plasma available for fractionation,<sup>313</sup> approximately 44,000 litres less than the 200,000 litre goal set by the Ministers of Health in 1981.

<sup>310</sup> Ex. 873, Vol. 205, Tab 8, p. 42 (*Inter-provincial Conference of Health Ministers, September 30, October 1, 1981*).

<sup>311</sup> Ex. 736, Tab 41, p. 331028 (*The Canadian Red Cross Society Blood Program 1995 Proposed Budget III: Program Overview*).

<sup>312</sup> Ex. 736, Tab 43, p. 4 (*Letter from Dr. Leclerc-Chevalier to Mr. George Weber, February 20, 1985*).

<sup>313</sup> Ex. 882, Vol. 214, Tab 1, p. 27150 (*Table entitled "Canadian Red Cross Blood Transfusion Service 1985 Program Budget Fractionation"*).



b) Connaught Wastage

226. Details concerning CLL waste and its ability to produce consistently reliable product are detailed under the heading "Self-Sufficiency in Plasma Processing - The Province's Strategy" below. However, it is important to note the negative effect that the CLL fractionation process had on the CRCS' efforts to obtain self-sufficiency in plasma collections.

227. The preferential treatment given to CLL by the provinces and the CBC had a direct impact on the availability of Factor VIII derived from Canadian source plasma. It was estimated that over the course of CLL's three year contract with the CRCS, it wasted nearly one year's equivalent of Factor VIII derived from Canadian source plasma (43,000 litres).<sup>314</sup> Placed in perspective, this wastage represented the entire supply of plasma collected by the CRCS through plasmapheresis during the years 1981 - 1985. CLL product yields were dismal when compared with those of U.S. fractionators. As an example, in the final year of its contract, CLL reported a product shortfall of approximately 2.6 million units.<sup>315</sup> Given the demand for product, the CRCS had no option but to attempt to alleviate the shortfalls with supplementary purchases of commercial plasma.<sup>316</sup>

c) Other Impediments to Self-Sufficiency

228. CBC funding impediments and the provinces' misguided support for CLL were the primary obstacles preventing CRCS from achieving self-sufficiency in plasma collections. However, there were other contributing factors. The move to heat-treated product resulted in

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<sup>314</sup> Ex. 629, CRC Vol. 26, Tab 15, p. 025987 (Addendum to October 26, 1984 Memo from Bill Mindell to Ontario and National CHS Officials "Crude Impact Analysis of Connaught Losses of Canadian Source Factor VIII 1981-1983").

<sup>315</sup> Ex. 628, Vol. 25, Tab 37 p. 48874 (Minutes of Meeting of BTS/Connaught Core Working Group, October 9, 1984).

<sup>316</sup> Ex. 758, Vol. 164, Tab 34, p. 143 (Memo from Mr. B. Mindell to Ontario Chapter CHS Factor Products Committee, October 26, 1984).



a 10% reduction in product yields.<sup>317</sup> In addition, voluntary product withdrawals and mandatory product recalls which occurred throughout the 1980s<sup>318</sup> contributed to shortages which, in turn, hampered efforts in obtaining self-sufficiency in plasma collections.

3) Self-Sufficiency in Plasma Processing - The Provinces' Strategy

a) CRCS Early Proposal for Canadian Fractionation Plant

229. By 1975, the CRCS recognized that existing domestic manufacturing capacity was inadequate to meet the present and future demand for fractionated blood products in Canada. In October 1975, the CRCS commissioned Dr. John Watt of the Scottish National Blood Transfusion Service to provide an overview and analysis of fractionation in Canada.<sup>319</sup> In his report, Dr. Watt concluded that the blood component manufacturing and distribution system in Canada was fragmented and inadequate. He noted from his international experience that countries lacking a central system for the procurement and distribution of blood products provided poor service to hospitals and physicians; a single, integrated system was required to ensure a high standard of care.<sup>320</sup> Based on the advice of Dr. Watt and its own Scientific Advisory Committee, the CRCS concluded that a single plasma fractionation facility should be built and operated as an integrated part of the national blood program.

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<sup>317</sup> Ex. 876, Vol. 208, Tab 10, p. 2853 (*Presentation entitled "Implications for the Canadian Red Cross Blood Transfusion Service" to the CBC Consensus Conference on Use of Heat-Treated Coagulation Factor Concentrates, Ottawa, December 10, 1984 by Dr. M. Davey*).

<sup>318</sup> For example, the CRCS destroyed a lot containing two million AHF units derived from Canadian source plasma when it was discovered it contained plasma from two donors who were potentially infected with hepatitis; and

Ex. 758, Vol. 164, Tab 34, p. 141 (*Memo from Mr. B. Mindell to Ontario Chapter CHS Factor Products Committee, October 26, 1984*).

<sup>319</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 26060-26061.

<sup>320</sup> Ex. 870, CBC Vol. 202, Tab 1, p. 2 (October 29, 1975 Memo from Watt to Perrault; regarding the Canadian Protein Fractionation study).



230. In November 1976, the CRCS proposed this measure at a meeting of senior officials from the health ministries of the ten provinces and the federal government.<sup>321</sup> The CRCS proposal was designed to streamline the blood delivery system in Canada. By co-ordinating all fractionation activities within the blood program, the CRCS believed it would be in the best possible position to secure a supply of high quality Canadian source plasma products. Economies of scale and improved efficiency obtained in the process would reduce costs, which in the long run, would provide substantial savings to the Canadian blood system. At this meeting the representatives accepted the CRCS proposal as compatible with the three fundamental principles of the Canadian blood system: protection of the voluntary donor system, self-sufficiency of blood products and gratuity of blood products. The CRCS was subsequently authorized to commission a planning study for the proposed plasma fractionation plant.<sup>322</sup>

231. In May 1977, the Conference of Deputy Ministers of Health established a Federal-Provincial Ad Hoc Committee on Plasma Fractionation to study the CRCS proposal and other options to ensure a continuous and adequate supply of blood products. The committee reported its findings almost two years later in February 1979. Only three provinces, Ontario, Quebec and Manitoba voted against the CRCS proposal. This was significant because these provinces had the only fractionation facilities existing in Canada at that time, namely, CLL, the Institute Armand Frappier and the Rh Institute in Winnipeg, whose futures would be in doubt in the event of a CRCS fractionation monopoly. However, the majority of committee members supported the CRCS proposal and recommended that one 200,000 litre fractionation plant be established and operated by the CRCS.<sup>323</sup> Despite this recommendation, the conference of Deputy Ministers of Health voted in March, 1979 to suspend consideration of a single fractionation facility until another Federal-Provincial Ad Hoc Committee was formed to consider the

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<sup>321</sup> Ex. 870, CBC Vol. 202, Tab 3, pp. 11 - 12 (List of Members who attended meeting November 23, 1976 Summary: Canadian Government Conference held on November 23, 1976).

<sup>322</sup> *Ibid*, p. 18; and

Ex. 606, CRC Vol. 3, Tab 17 (March 29, 1978 Report on a Plasma Fractionation Study for CRCS prepared by Surveyer, Nenniger & Chenevert Inc.).

<sup>323</sup> Ex. 870, CBC Vol. 202, Tab 15, p. 117 (February 7, 1979 Report: The Federal-Provincial Ad Hoc Committee on Plasma Fractionation).



development of a national blood policy.<sup>324</sup> This move effectively shelved the CRCS proposal and signalled that the Deputy Ministers of Health were unwilling to exclude existing Canadian fractionators and especially CLL from the future of fractionation in Canada.

b) Early Warnings About Connaught

232. The fractionation plant issue was much more than a dispute over who had the optimum proposal. For the CRCS, it was a matter of safety and efficiency. The provincial governments' course of action revolved around CLL and its ability to master increasingly sophisticated technology required to produce the new generation of fractionated blood products. The CRCS, the CHS and others had serious concerns about CLL's ability to meet this challenge. At the root of these concerns was the fear that pitting a voluntary system against a profit-motivated paid system (with CLL at its centre) would be more costly and result in more hepatitis infections.

233. As part of the University of Toronto, CLL had gained international acclaim for its past achievements in insulin and vaccine production.<sup>325</sup> After 1956, CLL fractionated plasma supplied by the CRCS to produce products including albumin, fibrinogen and gamma globulin. In 1972, the Canadian Development Corporation purchased CLL and the biological manufacturer's corporate structure changed.<sup>326</sup> CLL became a for-profit corporation which was a concern to the CRCS and others who viewed profits from the sale of blood products as inconsistent with the fundamental principle that Canada's blood system be based on gratuity of blood products. Unlike the University of Toronto, the Canadian Development Corporation emphasized the production of products for sale which would be profitable, expediting the CLL

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<sup>324</sup> Ex. 870, CBC Vol. 202, Tab 17, p. 137 para. d) (March 6 - 7, 1979 Minutes: *Meeting of the Conference of Deputy Ministers of Health held in Ottawa*).

<sup>325</sup> Ex. 605, CRC Vol. 2, Tab 19 (January 8, 1977 Journal Article: *Highlights and recommendations to CMA committee report on Connaught Laboratories Ltd.*, published in the *CMA Journal Volume 116*).

<sup>326</sup> Ex. 870, CBC Vol. 202, Tab 15, p. 103 (February 7, 1979 Report: *The Federal-Provincial Ad Hoc Committee on Plasma Fractionation*).



drift away from its roots as a research laboratory. In 1977, the Canadian Medical Association (hereinafter referred to as "CMA") prepared a report investigating wide spread public criticism about CLL, its organization, future role as a biological manufacturer, and the safety and efficacy of its products,<sup>327</sup> which was critical of CLL's diminishing interest in research and development:

The Committee finds that there is an increased emphasis on production rather than research and that emphasis is on short term research related to production rather than long term research related to new products. The Committee does not approve of this trend ....

In the twenty years since separation from the School of Hygiene ... research activity seems to have declined at "Connaught". Furthermore, there has not been adequate recruitment of young and competent scientists to engage in research. These trends seemed to have accelerated since Canadian Development Corporation, with its emphasis on the profitability of the operation, purchased "Connaught".<sup>328</sup>

234. The CMA found that the scientific technological base at CLL had slipped due to the deteriorating product facilities and practices. Noting that "... such a disturbing trend should be corrected",<sup>329</sup> the report summarized the consequences of CLL's decline:

...staff morale is low, public confidence in the institution has diminished and scientific performance is less than one would have predicted twenty years ago. The factors which have achieved this undesirable, *perhaps even dangerous*, situation for Canada include ambiguity of purpose, a declining commitment to research, and reluctance to renew optimally the plant.<sup>330</sup> (emphasis added)

235. CLL's organizational and scientific problems described in the CMA report were consistent with CRCS observations of CLL poor performance during the 1970's. Between 1974 and 1980, the CRCS dealt with four different presidents of CLL, with an intervening period of

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<sup>327</sup> Ex. 605, CRC Vol. 2, Tab 20 (January 10, 1977 Report: CMA Committee Report on Connaught Laboratories Ltd.).

<sup>328</sup> *Ibid*, pp. 29 and 67.

<sup>329</sup> *Ibid*, p. 27.

<sup>330</sup> *Ibid*, p. 55.



two years where there was no president at all. There was little evidence of CLL accountability given its private sector status and its lack of coherent management structure.<sup>331</sup>

236. CLL also drew criticism for production problems and its albumin export policy. In 1973, the CRCS reported that CLL production of albumin had been plagued by poor yields since the 1950's. CLL also had a track record of poor yields of hepatitis and tetanus immunoglobulins and difficulties with its small-batch fractionation process. The effect of these production problems were heightened in the period of 1973 - 1975 when Canada experienced an acute shortage of albumin. During the same period, CLL, the sole manufacturer of albumin in Canada, continued to export albumin for international sale without the CRCS knowledge or consent.<sup>332</sup>

237. Hemophiliacs also doubted CLL's potential to overcome its past production problems.<sup>333</sup> News reports at the time confirmed that hemophiliacs and the CHS had concerns about CLL ability to produce high quality Factor VIII in sufficient quantities.<sup>334</sup> Like the CRCS, hemophiliacs recognized the harm that could result if CLL was allowed to commercialize Canada's blood system. In 1980, CLL made known its intent to move to a system of paid plasma donations, a controversial plan seen by many as posing a dangerous risk to the safety of Canada's blood supply.<sup>335</sup>

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<sup>331</sup> Ex. 611, CRC Vol. 8, Tab 36, p. 4 (October 22, 1980 Minutes: Meeting with the CRCS and the Chapin Key Committee in Ottawa).

<sup>332</sup> Ex. 610, CRC Vol. 7, Tab 10, p. 1 (January 17, 1980 Proposal: Plasma Fractionation in Canada - Proposal for a Solution in 1980; prepared for the Special Ad Hoc Committee on Plasma Fractionation by Dr. Zipursky).

<sup>333</sup> Evidence of Dr. Inwood, Hemophilia Treater, pp. 33604 - 33605.

<sup>334</sup> Ex. 611, CRC Vol. 8, Tab 11 (September 17, 1980 News Articles).

<sup>335</sup> Ex. 611, CRC Vol. 8, Tab 3 (July 25, 1980 Letter from H. Tellier to The Honourable Monique Bégin); see also Exhibit 611, CRC Volume 8, Tab 11 (September 13, 1980 *Globe and Mail* News Article).



238. Other groups who supported the CRCS position on fractionation included the Canadian Hospital Association, the Canadian Association of Pathologists, the Canadian Nurses' Association, and the Association for Immunology.<sup>336</sup>

c) **Provincial Governments Force CRCS to Contract with Connaught**

239. Before CLL obtained its Factor VIII licence in 1979, there was no Canadian fractionator licensed to manufacture Factor VIII. In order to satisfy hemophiliacs' growing demand for this revolutionary product, the CRCS sought out a U.S. fractionator to process volunteer CRCS plasma.<sup>337</sup> The first CRCS contract for Factor VIII was filled during 1978-1979 by Hyland Laboratories of California, whose product yields consistently exceeded minimum contract specifications. The CRCS was sufficiently impressed by Hyland's product, that it was one of three fractionators from which the CRCS requested tenders to supply more product following the completion of the initial Hyland contract. The other two fractionators were Cutter Laboratories of California and CLL.<sup>338</sup>

240. The CRCS was not impressed by the CLL tender. It arrived late, was not set out in the proper form and failed to indicate any evidence of its manufacturing capacity for Factor VIII. CLL's price quotation was second in the field but was still several million dollars higher than the lowest bid submitted by Cutter.<sup>339</sup> Even apart from the cost consideration, the CRCS was mindful of its past problems with CLL and had serious doubts about its ability to manufacture large quantities of plasma. In light of these concerns, the CRCS decided to award

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<sup>336</sup> Ex. 607, CRC Vol. 4, Tab 14 (July 20, 1978 CRCS Memo from F.H. Badgley, Assistant National Commissioner to National Commissioner and Chairman of National Executive); see also Exhibit 608, CRC Volume 5, Tab 23 (May 11, 1979 Memo from Dr. Perrault to H. Tellier).

<sup>337</sup> Ex. 711, p. 37 (CRCS Report to the Canadian Haematology Society: *The Canadian Red Cross Blood Programme from 1974 to 1990*).

<sup>338</sup> Ex. 608, CRC Vol. 5, Tab 16, p. 2 (April 27, 1979 Memo from Perrault to Tellier).

<sup>339</sup> *Ibid.*, p. 2.



the contract to Cutter.<sup>340</sup> On June 6, 1980, the CRCS received a telex from Mr. D.C. McNaught, chair of the Federal-Provincial Program and Budget Review Committee providing what appeared to be appropriate authorization to proceed with the Cutter contract. The telex stated:

The Chairman of the Ad Hoc Committee of Deputy Ministers on Blood and Blood Products has advised that the *consensus of the provinces is to accept* the tender of Cutter Laboratories. Therefore, *I am authorized* by Mr. Chatfield to advise the Red Cross Society to proceed with the contract with Cutter Laboratories ....<sup>341</sup> (emphasis added)

Pursuant to this telex, the CRCS signed a contract with Cutter.

241. Despite Mr. McNaught's telex, the CRCS was subsequently forced by the provinces to cancel its contract with Cutter in order to satisfy the Ontario government's desire to promote the interests of CLL. In September 1980, representatives from the Ontario government met with the CRCS and voiced their strong objection to the Cutter contract. Contrary to Mr. McNaught's telex, there had been no consensus as Ontario, British Columbia and Nova Scotia objected to the Ad Hoc Committee of Deputy Ministers' decision to endorse the Cutter contract.<sup>342</sup> Ontario subsequently adopted the position that the Ad Hoc Committee acted beyond its mandate in this regard and that therefore, the CRCS lacked the appropriate authority to contract with Cutter.<sup>343</sup>

242. Clinging to its belief that CLL was the appropriate vehicle to assure Canadian self-sufficiency in plasma products, the Ontario government pressed the CRCS to cancel its

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<sup>340</sup> Ex. 610, CRC Vol. 7, Tab 37 (May 4, 1980 Minutes of the Special Ad Hoc Committee on the Plasma Fractionation Contract).

<sup>341</sup> Ex. 610, CRC Vol. 7, Tab 41 (June 6, 1980 Telex from McNaught to Perrault).

<sup>342</sup> Ex. 611, CRC Vol. 8, Tab 7 (September 5, 1980 Letter from Dyer to Morgan).

<sup>343</sup> Ex. 871, CBC Vol. 203, Tab 8, p. 69 (September 29, 1980 Transcript: Health Ministers Meeting; Regarding Plasma Fractionation Facilities).



contract with Cutter as soon as possible and redirect its plasma to CLL for processing.<sup>344</sup> Motivated by their political interest in protecting 50 jobs at CLL,<sup>345</sup> the Ontario government representatives threatened the CRCS with legislation to prevent it from exporting its plasma to the U.S. They also made threats to withdraw Ontario's \$19 million contribution to the CRCS budget, which would impose an impossible financial burden on the Canadian blood system.<sup>346</sup> For D.M. Allan, Assistant Deputy Minister of Industry (Ontario), the issue became personal. Clearly upset about the CRCS contract with Cutter, Mr. Allan was reported to have said:

You have really blown it, baby. If you think you are going to get a fractionation facility. No way.<sup>347</sup>

243. As a result of the considerable pressure applied by the Ontario government, the Cutter contract and its impact on CLL was re-visited at the September 29 - 30, 1980 meeting of the Federal-Provincial Ministers of Health. Notes from the first day of those proceedings indicate that a joint Federal-Provincial Committee was to be formed to review the fractionation issue. However, on the second day of the proceedings, in the absence of the Federal Minister of Health, the provinces decided to form their own committee, which excluded input from the Federal Minister.<sup>348</sup>

244. The new Provincial Committee, chaired by Dr. Chapin Key, Deputy Minister of Health for British Columbia, reviewed the Cutter contract issue and attempted to evaluate the long term prospects of Canada's fractionation industry. It was no coincidence that the Ontario

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<sup>344</sup> Ex. 611, CRC Vol. 8, Tab 7 (September 5, 1980 Letter from Ontario Assistant Deputy Ministers A.H. Dyer and D.M. Allan to Ian Morgan, CRCS).

<sup>345</sup> Ex. 611, CRC Vol. 8, Tab 19 (CRCS Notes of September 15, 1980 meeting between CRCS and Ontario Deputy and Assistant Deputy Ministers of Health).

<sup>346</sup> Ex. 709 (September 5, 1980 Report of CRCS meeting with representatives of the Province of Ontario); and Evidence of Drs. Perrault, former National Director BTS, and Davey, former Assistant National Director, BTS, pp. 26252 - 26255.

<sup>347</sup> Evidence of Drs. Perrault, former National Director BTS, and Davey, former Assistant National Director, BTS, pp. 26252 - 26255.

<sup>348</sup> Ex. 611, CRC Vol. 8, Tab 25 (CRCS Notes of September 29 - 30, 1980 Meeting of the Ministers of Health).



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government was the genesis of this committee, whose mandate specifically excluded consideration of the CRCS fractionation plant proposal.<sup>349</sup> The provincial Ministers justified this decision as a course of action promoting the fundamental principles of a voluntary, self-sufficient and gratuitous Canadian blood system.<sup>350</sup> However, it was clear to the CRCS that the provinces, led by Ontario, were guided more by politics and special interests than by scientific and economic merit.<sup>351</sup> The Ontario government's fixation with CLL was the subject of testimony of James Kreppner, a hemophiliac who summarized the issue:

Given the state of knowledge at the time, the Ontario government should have stopped fixating on the inefficient Connaught Laboratories, as I mentioned earlier. I believe this was done in order to gain votes by increasing employment under the guise of making us self-sufficient in fractionation. There is no point in being self-sufficient in fractionation; the point is that we want a safe blood supply. The point is that we must distinguish between self-sufficiency in fractionation and self-sufficiency in Canadian-sourced plasma which is understood to be safer.

If you can't fractionate efficiently, send it to someone who can fractionate instead of wasting all that Canadian blood, which is what I believe happened.<sup>352</sup>

245. The CRCS lobbied the Chapin Key Committee to re-examine the substantial merits of a CRCS operated fractionation plant. At a meeting with the Committee on October 22, 1980, Dr. Perrault presented the case for an integrated national blood system. He emphasized the CRCS concerns about CLL past inefficiencies and the negative impact that a fragmented system would have on the donor base. The CRCS was sceptical about its efforts to persuade the Committee given the Committee's own candid admission that the fractionation issue "... had become totally political."<sup>353</sup>

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<sup>349</sup> Ex. 871, CBC Vol. 203, Tab 9, p. 90 (*Chairman's Statement of Disposition of Agenda Items, September 30 - October 1, 1980, Interprovincial Conference of Health Ministers*).

<sup>350</sup> *Ibid.* p. 91.

<sup>351</sup> *Evidence of Dr. Davey, former Assistant National Director BTS*, pp. 27062 - 27065.

<sup>352</sup> *Evidence of James Kreppner, Hemophiliac*, pp. 4000 - 4001.

<sup>353</sup> Ex. 611, CRC Vol. 8, Tab 36, p. 10 (CRCS Minutes of October 22, 1980 Meeting with Chapin Key Committee).



246. The "political" factor was acknowledged in the Chapin Key Committee's report to the Provincial Ministers of Health Conference on December 15, 1980. The Committee ruled out the CRCS proposal and recommended that CLL and the Institut Armand Frappier assume the role of Canada's main fractionators, regardless of the added cost. The report stated:

Assuming that Connaught Laboratories will continue as a long-term fractionator, the Committee also believes that *the most economical choice of one plant must be compromised in view of the interest among several provinces in developing expertise in fractionation* ... It is, therefore, recommended that:

FROM A TECHNOLOGICAL DEVELOPMENT, ASSURANCE OF SUPPLY AND A POLITICAL POINT OF VIEW, AT LEAST TWO SEPARATE FRACTIONATION PLANTS SHOULD BE DEVELOPED IN CANADA, EVENTHOUGH THERE PROBABLY WOULD BE AN ASSOCIATED FINANCIAL PENALTY.<sup>354</sup> (emphasis added)

The Committee went on to conclude that future fractionation should be limited to a maximum of two facilities in Canada because, based on its analysis, there was a substantial cost penalty associated with the three plant option which "... did not offer any major advantages over two facilities".<sup>355</sup>

247. The Chapin Key Committee also recommended that the Cutter contract be renegotiated to allow for the diversion of plasma to CLL for fractionation. The Committee recognized that this would likely result in a substantial penalty under the existing contract but noted that Ontario had already agreed to pay any additional costs of re-routing plasma to CLL.<sup>356</sup>

248. The Chapin Key Committee recommendations were unanimously accepted by the provincial Ministers of Health with the added proviso that the Rh Institute be included in the list of Canadian fractionation facilities.<sup>357</sup> The CRCS found this decision particularly surprising

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<sup>354</sup> Ex. 611, CRC Vol. 8, Tab 40, p. 70 (November 24, 1980 Chapin Key Committee Report to the Provincial Ministers of Health, Received by Conference of Health Ministers, December 15, 1980).

<sup>355</sup> *Ibid*, p. 71.

<sup>356</sup> *Ibid*, pp. 64 and 74.

<sup>357</sup> Ex. 871, CBC Vol. 203, Tab 12, p. 33 (December 15 - 16, 1980 Transcript: Interprovincial Conference of Ministers of Health).



given the Chapin Key Committee's express recommendation against three facilities. At that time, the CRCS suspected that the Rh Institute was added as a matter of political expediency. In retrospect, this view seems reasonably supported by a review of the transcript of the provincial Ministers of Health meeting.<sup>358</sup>

249. Following the meeting of the provincial Health Ministers, the CRCS issued a press release indicating its extreme displeasure with the Ministers' decision on the fractionation issue, a decision which made no economic sense and posed a potential health risk for recipients:

The Canadian Red Cross Society is shocked by the Provincial Health Ministers' decision to choose three plants for the fractionation of blood plasma in Canada, while ignoring the proposal of the Red Cross Society.

The volume of plasma, which can be collected from Canadians on a non-profit basis, is sufficient for only one facility to operate efficiently and economically. In fact, the Society says it would be irresponsible if it were to send its plasma to these untried facilities for processing into the products required daily for the treatment of Canadians. We cannot in good faith endanger the health of Canadians by entrusting large volumes of our plasma to these facilities...<sup>359</sup>

Despite the defiant tone of its press release, the CRCS had no choice but to accept the reality that CLL, regardless of its many flaws, was about to be granted a large role in the fractionation of Canadian plasma. Pursuant to the provincial Health Ministers' direction, the CRCS was forced to renegotiate its contract with Cutter and, starting in 1981, initiated shipments of fresh frozen plasma to CLL for the manufacture of Factor VIII.

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<sup>358</sup> *Ibid.*

<sup>359</sup> Ex. 612, CRC Vol. 9, Tab 10 (December 16, 1980 Red Cross Press Release "Red Cross Shocked by Health Ministers' Decision - But Not Ready to Give Up Yet").



d) Connaught Production/Product Problems

250. CLL processed CRCS fresh frozen plasma between 1981 and 1984 for approximately three years. During that period, CLL was plagued by a host of production problems that confirmed the fears of the CRCS and hemophiliacs surrounding CLL's ability to produce high quality Factor VIII. Serious product deficiencies were evident soon after the CRCS began distributing CLL manufactured Factor VIII in February 1981. Numerous factors including antiquated plant and equipment, limited physical capacity for processing and general lack of expertise combined to produce product yields which were consistently below minimum contract specifications.<sup>360</sup>

251. Unfortunately, the problems could not be avoided by simply diverting plasma to another Canadian fractionator. Despite the hopes of the provincial Ministers, the Institut Armand Frappier fractionation plant never materialized and the Rh Institute plant never reached full operational status.<sup>361</sup> As such, CLL, despite its problems, was the only available Canadian option.

252. CLL production problems were a recurring agenda item at joint CRCS/CLL Technical Working Group meetings. The CRCS initiated a special Ontario Fractionator/Supplier/ User Group to specifically address the mounting complaints from hemophiliacs who experienced first-hand the effects of CLL's product. The range and magnitude of CLL manufacturing problems are illustrated by the partial list set out below:

- Utilization of 30 year old technology including an "open vat" system susceptible to atmospheric contamination and poor controls;<sup>362</sup>

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<sup>360</sup> Ex. 627, CRC Vol. 24, Tab 33 (August 2, 1984 Memo from Dr. Naylor to Dr. Perrault re: Specific problems associated with Connaught's Production of Factor VIII Concentrate).

<sup>361</sup> Ex. 711, p. ix (CRCS Report to the Canadian Haematology Society: *The Canadian Red Cross Blood Programme from 1974 to 1990*).

<sup>362</sup> Evidence of Dr. Perrault, former National Director BTS and Dr. Davey, former Assistant National Director BTS, pp. 26053 - 26057.



- Antiquated facilities providing a less than sterile environment for the processing of plasma - a plant tour revealed chipped paint throughout, rusty processing pipes, non stainless steel drain boards, and bags of frozen plasma being ripped opened with wooden handled carpet knives;<sup>363</sup>
- Poor solubility of product requiring upwards of one hour for concentrate to dissolve - prompting one hemophilia official to note:

The waiting process is extremely painful when a hemophiliac needs an injection as soon as possible to treat a bleed. The extra time he has to wait [for the product to dissolve] the more pain he must endure, and the longer the bleed is prolonged, the more damage that may result to the joint;<sup>364</sup>
- Similar complaints about poor product solubility moved the CRCS to demand assurances from CLL that Ontario hemophiliacs "not be used as test subjects on which CLL could evaluate and develop Factor VIII concentrates";<sup>365</sup>
- Presence of rubber particles in reconstituted Factor VIII resulting from "coring" occurring during the reconstitution procedure indicating needle size problem or defect in composition of vial stopper;<sup>366</sup>
- Product crystallized in bottle; product remained cloudy after mixing;<sup>367</sup>
- Diluent packaging deficiencies; bottles received broken from manufacturer;<sup>368</sup>
- Excessive vacuum in bottles causing problems with drawing the solution into syringe, even for persons of reasonable strength;<sup>369</sup>

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<sup>363</sup> Evidence of Bill Mindell, CHS Member (Ontario Chapter) pp. 32370 - 32373.

<sup>364</sup> Ex. 750, CBC Vol. 157, Tab 64 p. 247 (August 1, 1981 Letter from Mark George, Chair of Central Western Ontario Auxiliary CHS to E.T. Gurney, Executive Director CHS re: Connaught Product Complaints); see also Evidence of Dr. Davey, former Assistant National Director, BTS, pp. 26360 - 26362.

<sup>365</sup> Ex. 614, CRC Vol. 11, Tab 39 p. 4 (July 21, 1982, Minutes of CRCS/CLL Working Group Meeting).

<sup>366</sup> Ex. 750, CBC Vol. 157, Tab 70, p. 264 (October 20, 1981 Summary Notes of CRCS/CLL Meeting to Discuss User Complaints of CLL Factor VIII).

<sup>367</sup> Ex. 614, CRC Vol. 11, Tab 39 (July 21, 1982 Minutes of CRCS/CLL Working Group).

<sup>368</sup> Ibid.

<sup>369</sup> Ex. 750, Vol. 157, Tab 64, p. 247 (August 1, 1981 Letter from Mark George, Chair of Central Western Ontario Auxiliary CHS to E. T. Gurney, Executive Director, CHS re Connaught Product Complaints).



- Insufficient vacuum in bottles causing vial stoppers to pop off when removing metal cap and top rim of bottle to break off:<sup>370</sup>
- Product packaged in very small unit sizes requiring numerous bottles per injection and causing logistical problems handling sufficient amount of sterile water to dissolve product:<sup>371</sup>
- Nitrogen freeze drying equipment failures resulting in disruption of processing and plasma volume short fall:<sup>372</sup>
- Pyrogenic (bacterial) contamination of Factor IX complex reflecting deficient handling procedures:<sup>373</sup>
- Lack of uniformity of protein and fibrinogen content and ABO isoagglutinin titres;<sup>374</sup>
- Delay in development of a high purity Factor VIII product;<sup>375</sup>
- Failure to provide CRCS with adequate notice of plant shut down disrupting supply schedule:<sup>376</sup>
- Delays in release of product due to low potency, viscous appearance and high protein content:<sup>377</sup>

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<sup>370</sup> Ex. 614, CRC Vol. 11, Tab 39 (July 21, 1982 Minutes of CRCS/CLL Working Group).

<sup>371</sup> Ex. 750, CBC Vol. 157, Tab 64 p. 246 (August 1, 1981 Letter from Mark George, Chair of Central Western Ontario Auxiliary CHS to E.T. Gurney, Executive Director CHS re: Connaught Product Complaints).

<sup>372</sup> Ex. 613, CRC Vol. 10, Tabs 29 p. 3 and 30 p. 5 (January 12, 1982 Minutes CRCS/CLL Scientific Liaison Committee); and

Ex. 614, CRC Vol. 11, Tab 5 (February 9, 1982 Memo from D.H. Naylor to J.B. Derrick re: CRCS Summary of February 8, 1982 Meeting).

<sup>373</sup> Ex. 614, CRC Vol. 11, Tab 5 p. 48605 (February 9, 1982 Memo from D.H. Naylor to J.B. Derrick re: CRCS Summary of February 8, 1982 Meeting).

<sup>374</sup> Ex. 615, CRC Vol. 12, Tab 21, p. 2 (October 26, 1982 Internal Minutes of CRCS/CLL Meeting).

<sup>375</sup> *Ibid*, p. 2.

<sup>376</sup> *Ibid*.

<sup>377</sup> Ex. 615, CRC Vol. 12, Tab 21 (October 26, 1982 Minutes of CRCS/Connaught Working Group).



253. Numerous hemophiliacs suffered physical reactions, ranging from mild to severe, following the use of CLL's product. The multitude of reactions prompted some hemophiliacs to stop using CLL Factor VIII. The following complaints were typical:<sup>378</sup>

- Redness and sharp pain in arm accompanying infusion;
- Blurred vision;
- Headaches;
- Light headiness;
- Dizziness;
- Disorientation;
- Fainting;
- Black out spells lasting up to 10 minutes;
- Facial flushing;
- Spots before the eyes;
- Change in body pressure;
- Pounding sensation in veins;
- Hives; and
- Chills.

254. In his testimony, Bill Mindell, former Chair of the Ontario Chapter - CHS Factor Products Subcommittee, described CLL performance throughout the 1981 - 1984 period as "pathetic".<sup>379</sup> Correspondence written by Mr. Mindell in November 1984 emphasized its inability to produce a reliable product:

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<sup>378</sup> Ex. 758, CBC Vol. 164, Tab 40, p. 167 (Attachment to October 31, 1984 Letter from Bill Mindell to Dr. Naylor);

Ex. 750, CBC Vol. 157, Tab 64 (August 1, 1981 Letter from Mark George, Chair of Central West Ontario and Auxiliary CHS to E.T. Gurney, Executive Director CHS re: Connaught Product Complaints); and

Ex. 750, CBC Vol. 157, Tab 65 (August 31, 1981 Letter from Matthew Maynard to Dr. Inwood, Medical Director of S.W.O.H.P.).

<sup>379</sup> Evidence of Bill Mindell, CHS Member (Ontario Chapter), pp. 32370 - 32373.



Connaught has consistently demonstrated not only a lack of expertise in this field and the inability to produce an acceptable product for therapeutic use, but a total lack of corporate commitment to doing anything about it over the last four to five years. And that's in spite of the political backing and the mandate they received!<sup>380</sup>

#### e) Connaught's Wastage Created Supply Problems

255. The ongoing product and production problems had a negative impact on the supply of Factor VIII in Ontario, where CLL's product was distributed. CLL's inability to master the AHF process resulted not only in reduced product yields but also in a substantial waste of precious volunteer Canadian source plasma. Product losses over the course of the three year contract were estimated to be a staggering one year equivalent of all Factor VIII derived from Canadian source plasma - 215,000 blood donations or 43,000 litres of fresh frozen plasma.<sup>381</sup> This wastage upset the delicate balance of supply and demand in the Canadian plasma market and forced the CRCS to become increasingly dependent upon U.S. source commercial plasma. The direct economic cost of this loss of Factor VIII from Canadian source plasma was estimated at \$1.9 million. However, as one CHS official observed, the non-economic costs associated with reliance upon riskier U.S. product were also of concern:

It also should be noted that these [economic] costs are the least important costs associated with Connaught's inefficiencies. The most important cost is the loss of valuable safe Canadian source plasma for use in the treatment of hemophilia. The future costs of disease or even death associated with exposure to plasma obtained from higher risk sources in the U.S. may never be calculated.<sup>382</sup>

256. Delivery and production schedule interruptions by Connaught and its recurring low product yields forced Connaught to make up the shortfall by purchasing and distributing

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<sup>380</sup> Ex. 759, CHS Vol. 165, Tab 18, p. 656 (November 20, 1984 Letter from Bill Mindell to Gerry Woloschuk).

<sup>381</sup> Ex. 629, CRC Vol. 26, Tab 15 p. 025987 (Addendum to October 26, 1984 Memo from Bill Mindell to Ontario and National CHS Officials entitled "Crude Impact Analysis of Connaught Losses of Canadian Source Factor VIII: 1981 - 1983").

<sup>382</sup> Ex. 629, CRC Vol. 26, Tab 15, p. 025986 (October 26, 1984 Memo from Bill Mindell to Ontario and National CHS Officials re: Factor VIII Shortages in Canada).



increasing amounts of commercial product. In Toronto, where there was a high concentration of product use, the ratio of commercial versus non-commercial concentrates (normally a 50/50 mix) was seriously disturbed by the CLL supply problems. At one point, the CRCS Toronto Centre was distributing approximately eight times more commercial product than volunteer CRCS source product.<sup>383</sup>

257. CLL's role in supplying product from U.S. source plasma came to an abrupt halt in September 1983, when Dr. Davey discovered that CLL had supplied product derived from plasma of U.S. prisoners. The CLL supplementary contract was immediately cancelled and the CRCS initiated its own withdrawal of all existing product associated with CLL supplementary purchases.<sup>384,385</sup>

258. Despite numerous meetings and process modifications, CLL production problems continued. In August 1983, Dr. Naylor wrote to the Ontario Medical Directors notifying them that as a result of CLL's continuing technical problems, the CRCS Ontario Centres would receive Factor VIII from part of the CRCS strategic reserve of Hyland product. Switching to the Hyland product allowed the CRCS to build up an inventory of CLL product to offset future interruptions in supply.<sup>386</sup>

259. Ontario hemophiliacs shared the view that CLL was partly responsible for the acute shortage of product. The October 1984 edition of *Hemophilia Ontario* cited CLL continuing production problems which "... resulted in reduced yields of Factor VIII and delays in the delivery of concentrate."<sup>387</sup>

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<sup>383</sup> Ex. 620, CRC Vol. 17, Tab 44, p. 040267 (August 26, 1983 Letter from Dr. Naylor to Dr. Strawczynski, Chair MSAC CHS).

<sup>384</sup> Ex. 621, CRC Vol. 18, Tab 11 (September 7, 1983 Letter from Dr. Davey to Mr. Reilly, Vice-President, CLL).

<sup>385</sup> Evidence of Dr. Perrault, former National Director BTS and Dr. Davey, former Assistant National Director BTS, pp. 26458 - 26469.

<sup>386</sup> Ex. 620, CRC Vol. 17, Tab 49 (August 30, 1983 Memo from Dr. Naylor to Ontario Medical Directors).

<sup>387</sup> Ex. 758, Vol. 164, Tab 16, p. 072 (October 1984 Edition of *Hemophilia Ontario*).



260. Despite efforts by CRCS to provide assistance, CLL was unable to overcome its production problems. The mounting frustration of the CRCS was evident in an August 2, 1984 letter from Dr. Perrault to Steven Dreezer, notifying the Ontario Ministry of Health that CLL unacceptable low product yields were having a direct effect on the supply of Factor VIII throughout the country. An enclosed memo from Dr. Naylor indicated that CLL yields of Factor VIII were approximately half those obtained by other fractionators.<sup>388</sup>

f) **Connaught's Compensation Package**

261. The CRCS suspended all shipments of plasma to CLL in November 1984 following the BoB directive to implement heat-treated product.<sup>389</sup> Because CLL was not licensed to manufacture heat-treated product, CRCS sent the plasma to Cutter instead. This diversion of plasma prompted the CBC to authorize CRCS to negotiate an appropriate relief package for CLL's loss of the supply contract.<sup>390</sup> CLL, portraying itself as a victim of the BoB's decision, requested financial support to cover costs for capital investment, overhead, research and development, until such time as it developed its own heat-treatment process.<sup>391</sup> Pursuant to a CBC direction, the CRCS negotiated a six month assistance package representing payment of nearly \$1 million during the period May 1985 - October 1985.<sup>392</sup> The CBC

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<sup>388</sup> Ex. 627, CRC Vol. 24, Tab 34 (August 2, 1984 Letter from Dr. Perrault to Steven Dreezer with enclosed August 2, 1984 Memo from Dr. Naylor to Dr. Perrault).

<sup>389</sup> This is fully discussed in the Heat Treatment Section.

<sup>390</sup> Ex. 632, CRC Vol. 29, Tab 3 (January 21, 1985 Telex from Denise Leclerc-Chevalier to Dr. Perrault).

<sup>391</sup> Ex. 632, CRC Vol. 29, Tab 4, (January 22, 1985 Memo from Dr. Perrault to CRCS Director, Blood Product Services).

<sup>392</sup> Ex. 632, CRC Vol. 29, Tab 8 (January 25, 1985 CRCS Report re: Financial Impact of Diversion of FFP to Cutter).



subsequently authorized two further extensions for a relief package totalling approximately \$1.4 million over an eleven month period.<sup>393</sup>

262. It is interesting to note the relative speed and ease with which the CBC approved the CLL financial assistance package. It stands out in stark contrast to the bureaucratic hurdles the CRCS faced during the same year when it sought funding approval from the CBC for implementation of anti-HIV testing. Further details regarding this issue are discussed later in these submissions under the heading "Anti-HIV Testing".

#### 4) Conclusion

263. Despite the CRCS efforts to obtain self-sufficiency in plasma collections, various external factors prevented this from occurring. The CRCS plan to gradually increase levels of collections leading to self-sufficiency was thwarted by the provinces through the CBC who pursued other priorities. Motivated by the short term financial benefit of pursuing cheaper, foreign supplementary purchases, self-sufficiency in plasma processing was instead emphasized. Domestic plasma processing is a worthy goal if quality is not compromised and it is motivated by concerns of security of supply. The CBC, however, employed the principle to achieve political ends. The CBC's strategy was destined to fail because it was premised on the misguided assumptions that the existing Canadian fractionators at that time were capable of producing high quality product, in the quantity demanded by Canadian hemophiliacs, and that it should and could be done by three fractionators.

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<sup>393</sup> Ex. 642, CRC Vol. 39, Tab 27 (January 29, 1986 Letter from Denise Leclerc-Chevalier to Dr. Perrault).

*Despite the financial assistance package, CLL experienced substantial delays in implementing a heat-treatment process. By international standards, the CLL fractionation division was relatively small and could not keep up with the rapid technological shift, nor did it have the necessary infrastructure or expertise to compete in the specialized world of fractionated biologicals. CLL eventually resumed manufacturing AHF in 1986. However, only a few lots of heat-treated product were produced before insurance and liability concerns forced the company out of the fractionation business.*



264. The CLL foray into the fractionation of Canadian plasma resulted not only in widespread shortages of AHF through 1981 to 1984, but also resulted in the waste of countless litres of precious volunteer Canadian source plasma which were lost during the failed attempts of CLL to master the complexities of the AHF manufacturing process. For each reprocessed or failed lot of AHF, the CRCS purchased replacement U.S. commercial product in order to maintain the delicate balance of supply and demand for factor concentrate in Canada. Under the guise of promoting Canadian self-sufficiency, the provincial governments, led by Ontario, forced the CRCS to contract with CLL. In the end, this strategy, motivated by political expediency, compromised the very goal it sought to achieve. There is little doubt that had the provinces heeded the early warnings of the CRCS and others, this excessive dependence upon imported clotting factor could have been avoided.<sup>394</sup>

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<sup>394</sup> Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27062 - 27065.



D. THE DELICATE BALANCE BETWEEN SUPPLY AND DEMAND:  
SHORTAGES AND OVER-UTILIZATION

265. The CRCS, as the collector and distributor of blood products in Canada, is responsible for providing blood and blood products to hospitals on demand. However, its ability to do so is dependent upon shifts in both the supply and demand for blood and blood products.

1) Supply: Maintaining Sufficient Collections

266. Only 4.5% of the adult population in Canada are blood donors. Yet approximately 330,000 persons a year require blood or blood products.<sup>395</sup> This puts the Canadian blood system in a precarious position. Even slight decreases in supply or increases in demand can upset the delicate balance and cause critical shortages:

...keeping in mind that when there is approximately 330,000 people a year who receive blood and blood products in one form or another, at that point, and nobody is here in the room to represent the other 329,000, but it is -- they were of concern. And we had to worry about that every day. So a major shortage, for example, if you have an impact of 2 to 3 per cent -- well, a 1 per cent decrease is 10,000 donations. And that is significant.<sup>396</sup>

267. Ensuring sufficiency of the blood supply is crucial. There has been an ongoing challenge for the CRCS to maintain a steady level of collections since 1978, when it began to battle continual blood shortages, particularly in the larger urban areas of Toronto, Montreal and

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<sup>395</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 27657-27660;*

*Evidence of Dr. Zuck, Member of Safety Audit Committee Panel, pp. 721-20722; and*

*Evidence of Dr. Blajchman, Hamilton Centre Medical Director, p. 19583.*

<sup>396</sup> *Evidence of Dr. Perrault, former National Director BTS, p. 27659.*



Vancouver.<sup>397</sup> Over-collection resulted in components being wasted because the volume of new donations was beyond the laboratory's processing capacity.<sup>398</sup> Surplus units became outdated before they could be used.<sup>399</sup> This wastage led to further shortages, such that surgery had to be cancelled.<sup>400</sup>

268. Efforts to recruit more donors were also hampered by the lack of Blood Donor Recruitment (hereinafter referred to as "BDR") resources as a result of budget restrictions by the CBC.<sup>401</sup> Shortages were often caused, not by a lack of donors, but by a lack of resources to recruit them.<sup>402</sup>

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<sup>397</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 27078-27079 and 30018-30019.

<sup>398</sup> Evidence of Léandre Laflamme, Director of BDR, Eastern Quebec, p. 15329.

<sup>399</sup> Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20231-20232.

<sup>400</sup> Evidence of Dr. Pinkerton, Director, Sunnybrook Hospital Blood Bank, pp. 3802-3803;

Evidence of Dr. Turner, Edmonton Centre Medical Director, p. 7668; and

Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20172-20173 and 20215-20218.

<sup>401</sup> Evidence of Léandre Laflamme, Director of BDR, Eastern Quebec, p. 15331;

Evidence of Linda Gauthier, Director of BDR, Western Quebec, pp. 15300, 15335;

Evidence of Dr. Guevin, former Medical Director Quebec Centre, p. 15922;

Evidence of Janet Jones, Board of Governors Panel, pp. 40221-40222;

Evidence of George Weber, Secretary General, Federation of National Red Cross/Red Crescent Societies, p. 40787; and

Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30044-30045.

<sup>402</sup> Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13852-13856;

Evidence of Lin Good, Board of Governors Panel, pp. 40281-40283;

Evidence of Dr. Schroeder, Winnipeg Centre Medical Director, pp. 9751-9754; and

Evidence of Dr. Gorelick, Halifax Centre Medical Director, pp. 12840-12841.



269. The CRCS strove to ensure that every unit of blood was used and not wasted. The national nature of the Canadian blood system permitted transfers of blood from a centre having a surplus of blood to a centre experiencing a shortage.<sup>403</sup> This was institutionalized in a few places. For example, parts of Northern Ontario were supplied by the Winnipeg Centre and the Lloyminster Saskatchewan area on the Saskatchewan-Alberta border was supplied by the Edmonton Centre.<sup>404</sup> However, in general, transfers of blood from centre to centre have always been considered a short-term emergency solution to the problem of chronic shortages in the larger urban centres. It was recognized that chronic shortages in an area must be remedied, so that a centre need not rely upon an uncertain supply of blood from another centre which is responsible for supplying its own hospitals first. Moreover, the distance between some centres can make such transfers impractical. The goal was to achieve regional self-sufficiency.<sup>405</sup>

270. For example, although the St. John's Centre consistently collected a surplus of blood throughout the 1980s,<sup>406</sup> this surplus was not sufficient to make up the shortages at the Vancouver, Montreal and Toronto Centres. Those centres accounted for 65% of all blood collections in Canada. However, St. John's could not be relied upon to regularly relieve shortages in the rest of the country. Flight delays due to weather conditions in Newfoundland could mean that components would be outdated before they reached their destination.<sup>407</sup> Therefore, such arrangements were only occasionally feasible to make up a small shortfall.

271. Moreover, transfers of blood across provincial borders were further complicated by the system of payments by the provinces for the blood program. Each province wanted the

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<sup>403</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 29276-29281, 29707-29712.*

<sup>404</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 29277-29278; and*

*Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8390-8391.*

<sup>405</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 29279; and*

*Evidence of Dr. Kaegi, former Toronto Centre Acting Medical Director, p. 34438.*

<sup>406</sup> *Evidence of Dr. Huntsman, St. John's Centre Medical Director, pp. 13817-13819, 13830-13840.*

<sup>407</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 29276-29281, 29707-29712.*



blood collected in its province to be used in that province, since it had paid for it. Therefore, transfers of blood across provincial borders were discouraged by the CBC; when it occurred, a paper adjustment was required at year end.<sup>408</sup>

## 2) Demand: Monitoring Utilization Trends

272. Sufficiency of collections was one factor about which the CRCS had to be continually vigilant. The CRCS was expected to supply blood and blood products on demand. However, its ability to affect the demand in hospitals, surgical transfusion practices, or hemophilia treater regimens, was limited. The CRCS had no direct control over, or responsibility for, blood usage at the hospital level.<sup>409</sup> It received monthly statistical reports about utilization, which enabled it to monitor trends and anticipate future needs.<sup>410</sup>

273. Nonetheless, CRCS medical staff have been active in educating users about the utilization of blood and blood products.<sup>411</sup> One of the primary means of education is the CRCS *Clinical Guide to Transfusion*, copies of which are provided to all hospital physicians, nurses and technicians, as well as medical students.<sup>412</sup> CRCS medical staff also regularly discuss appropriate utilization of blood products at hospital rounds and lectures to medical students.<sup>413</sup>

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<sup>408</sup> *Evidence of Dr. Perrault, former National Director BTS, pp. 29276-29281;*

*Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20280-20286;*

*Evidence of Dr. Huntsman, St. John's Centre Medical Director, p. 13836; and*

*Evidence of Claude Morin, National Administrator, CRCS BTS, 1981-1986, pp. 39862-39864 and 39687.*

<sup>409</sup> *Evidence of Dr. McClatchey, Physicians Panel (Ontario), pp. 20912-20913.*

<sup>410</sup> *Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 21340-21342.*

<sup>411</sup> *Evidence of Dr. Decary, Montreal Centre Medical Director, p. 16053.*

<sup>412</sup> *Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 473-474, 20278-20280.*

<sup>413</sup> *Evidence of Dr. Herst, Toronto Centre Medical Director, pp. 20278-20280, 21340-21342.*



CRCs Medical Directors have regular meetings with the hospital blood bankers, at which risks and benefits are discussed.

274. Apart from these efforts, the CRCs has no control over utilization or transfusion practices in hospitals. CRCs medical staff had regular meetings with hospital blood bankers, at which risks and benefits were discussed.<sup>414</sup> However, CRCs medical staff have not been invited to sit on hospital transfusion committees, which were struck to monitor blood usage and the transfusion practices of individual physicians. There has been overwhelming evidence from hospital blood bankers that hospital transfusion committees have been ineffective in both monitoring and controlling usage.<sup>415</sup>

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<sup>414</sup> *Evidence of Dr. Decary, Montreal Centre Medical Director, p. 16503.*

<sup>415</sup> *Evidence of Physicians Panel (Ontario), pp. 19129-19134;*

*Evidence of Dr. Pinkerton, Director, Sunnybrook Hospital Blood Bank, pp. 3713-3718;*

*Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, pp. 8432-8436;*

*Evidence of Dr. Alport, Regina Centre Medical Director, pp. 8991-8992;*

*Evidence of Dr. Mosley, Director of Transfusion Safety Study, pp. 25548-25549; and*

*Evidence of Dr. Read, Member of NAC AIDS and PAC AIDS, p. 20907.*



## II. DEVELOPING KNOWLEDGE OF THE RISK OF AIDS THROUGH BLOOD PRODUCT USE OR TRANSFUSION

### 1) Introduction

275. To appreciate the response of the medical, scientific and blood banking community to the problem of Acquired Immune Deficiency Syndrome (hereinafter referred to as "AIDS"), it is necessary to understand and analyze the evolution of knowledge of this syndrome during the 1980s. AIDS emerged as a disease unlike any other known in the history of human infectious diseases. Scientists had not previously encountered such an extraordinarily long latency period from exposure to the manifestation of symptoms. This hindered an accurate analysis of the natural history and course of the disease, as well as an appreciation of the risk to blood transfusion and clotting factor recipients. When the first reports of the condition known as AIDS arose in high-risk populations, scientists struggled to understand the nature, natural history and progression of this new disease. Scientists could only theorize about what was causing this unusual syndrome of immune deficiency in specific populations. Numerous theories surrounding the genesis of this syndrome and its progression were expounded. While many of these theories were later proven to be incorrect, it is imperative not to lose sight of the myriad of sometimes inconsistent hypotheses and studies of the emerging disease which contributed to the confusion during the 1980s. With the benefit of some fourteen years of hindsight and a greater understanding of the natural history of infection of HIV, we are still only partially able to delineate the natural progression of HIV infection to manifestation of the full range of symptoms of AIDS. It will only be with the benefit of hindsight, the full progression of time and observation of patients from infection to manifestation of disease that the spectrum of HIV infection and its effects will be understood.



2) The Decline of Infectious Diseases in the Western World

276. A decade prior to the first report of AIDS and the eventual discovery of the Human Immunodeficiency Virus (hereinafter referred to as "HIV") there was a naive confidence in the scientific and medical communities that fatal infectious diseases were a problem of the past as most had been virtually eliminated from the first world. It was widely believed that no further infectious diseases would be discovered.<sup>416</sup> Any newly recognized virulent diseases, such as ebola or lassa fever, were considered to be exceedingly rare exotic afflictions, which were understood to affect only particular populations in the third world.<sup>417</sup>

277. In North America overall health and life expectancy were dramatically improving. Nonetheless, some sexually transmitted diseases (hereinafter referred to as "STDs") had continued to spread rapidly through the first world population. It was known that gay men, in particular, suffered from high rates of venereal disease. Nevertheless, STDs were viewed by many as minor inconveniences that could be quickly and safely treated with antibiotics.<sup>418</sup>

278. Although there were known blood-borne diseases, in particular, malaria, syphilis and hepatitis, they were infrequent complications of transfusion and rarely resulted in the death of a patient. In North America, Hepatitis B testing was introduced in the early 1970's, rendering transfusion-associated Hepatitis B an almost non-existent phenomenon.

279. In the late 1970's, a new type of hepatitis, at first identified only as Hepatitis Non-A, Non-B (hereinafter referred to as "NANB") was observed. This condition was poorly understood, both in its infectiousness and its course of infection. Researchers were unaware of the potential long-term consequences of Hepatitis NANB, such as liver cancer. Only after the

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<sup>416</sup> Ex. 562, Tab 47, pp. 101-102 (Dr. Bruce Evatt, "AIDS Epidemic and Blood Safety: Changes in Attitudes from a Historical Perspective").

<sup>417</sup> Evidence of Dr. Korn, Chief Medical Officer of Health, Province of Ontario, pp. 2253-2255.

<sup>418</sup> Ex. 122, Vol. 50, Tab 1, p. 1 (Merv Walker, "The Clap Trap." The Body Politic April 1977).



natural history of the disease was followed and the virus identified, was the seriousness of Hepatitis NANB infection, now called Hepatitis C, realized.<sup>419</sup>

3) The Universal Paradigm of Disease Prior to AIDS

280. In the early 1980's the scientific community accepted a universal paradigm of the nature of disease: known infectious diseases followed a predictable pattern. Contact with an infectious agent led to a display of symptoms within a short period of time following infection. While an incubation period (also known as a latency period) was known to exist in all infectious diseases, most of them were fairly short. The exception was the Hepatitis B latency period, which was recognized as one of the longest and could take thirty to one hundred days from exposure to the virus before symptoms of infection would manifest.<sup>420</sup>

281. Diseases also had a definite marker or hallmark which was unique to the specific disease and indicated illness caused by a particular agent. One of the problems scientists first encountered with the AIDS syndrome was that, prior to immune testing and later antibody testing, there was no marker of the disease. The syndrome was identified by some mode of immune suppression in patients, such that they either developed common diseases (which are endemic in all populations but were easily overcome, like candidiasis) or they developed unusual diseases (such as Kaposi's sarcoma (hereinafter referred to "KS") and Pneumocystis Carinii Pneumonia (hereinafter referred to as "PCP"), which had rarely been seen in young and apparently healthy patients).

282. It was recognized that infectious diseases followed a particular pattern of morbidity. Most people infected with an agent or exposed to a virus mounted an immune

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<sup>419</sup> *Evidence of Dr. Feinman, Co-Director, Hepatitis Research Laboratory, The Toronto Hospital, pp. 22959-22960; and*

*Evidence of Dr. Blajchman, Hamilton Centre Medical Director, pp. 22961-22962.*

<sup>420</sup> *Evidence of Dr. MacPherson, former Medical Director of Health, City of Toronto, pp. 3497-3498.*



response enabling their body to fight the agent. Antibodies to the infectious agent developed to enable the body to become resistant to any further infection. Moreover, not everyone exposed to the virus would suffer from the infection. Often, only a minority of people infected would develop the disease and, of those, only an extremely small number would die of their illness.

283. By the 1970's, as the scientific understanding of the human immune system became more sophisticated, the intricate mechanics of the immune system were studied on a cellular level.<sup>421</sup> By 1981, technological advances enabled scientists to identify the specific proteins present on the surface of blood cells and Monoclonal antibodies were observed for the first time. The number of CD-8 and CD-4 cells present in the human body could now be ascertained.<sup>422</sup>

284. Overall, these advances enabled researchers to ascertain the general health of a person's immune system, however, using this technology was prohibitively expensive. In 1980, the equipment which would allow a facility to test for T4-T8 ratios cost approximately \$100,000, consumed a great deal of space in the hospital setting, and required a researcher at the PhD level to perform the analysis.<sup>423</sup>

#### 4) The Emergence of Opportunistic Infections in Gay men

285. During the advent of these emerging technologies, the first cases of opportunistic infections in unusual populations were reported. Simultaneously, a new strain of the herpes virus, Herpes Simplex II, emerged and was rapidly spreading through North America and Europe. The first reports of KS and PCP coincided with the emergence of "yuppie flu", later

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<sup>421</sup> *Evidence of Dr. Davey, former Assistant National Director BTS, p. 26536. [This relates to immune dysfunction studies done on hemophiliacs in the 1970's with "relative to today imprecise tools"].*

<sup>422</sup> *Evidence of Dr. Francis, Epidemiologist, pp. 21553-21555.*

<sup>423</sup> *Evidence of Dr. Francis, Epidemiologist, pp. 21804; and*

*Evidence of Dr. Tsoukas, Montreal General Hospital, pp. 39550-39552.*



termed "chronic fatigue syndrome", which was thought to be caused by the Epstein-Barr virus (hereinafter referred to as "EBV").

286. Scientists initially had only a set of symptoms by which to determine whether or not a patient was suffering from the syndrome. The very label, Acquired Immune Deficiency Syndrome, indicated that scientists could not readily identify a disease. Rather, it described the occurrence of a number of known diseases in patients, who did not fit the usual patient profile. A syndrome is not a disease entity *per se*, but rather a collection of findings which give the appearance of disease<sup>424</sup>.

287. Prior to the reports of 'PCP' in gay men, pneumonia of this nature was seen predominantly in cancer patients undergoing chemotherapy or in patients who had received immuno-suppressive therapy following organ transplants. Similarly, cases of 'KS' were usually reported only in patients who had undergone kidney transplants and had been treated with immuno-suppressive drugs, or, in certain populations such as elderly Jewish or Mediterranean men.<sup>425</sup>

288. In June of 1981, the *Morbidity and Mortality Weekly Report* (hereinafter referred to as "MMWR") described five unusual cases of PCP in homosexual male patients, who lived in the Los Angeles, California area. All five patients also had cytomegalovirus infection (hereinafter referred to as "CMV"), which was known to induce abnormalities in the cellular immune function of healthy people. CMV was highly prevalent among gay men. In one study reported in the *MMWR*, up to 94% of 190 gay men studied had CMV.<sup>426</sup> The *MMWR* suggested that CMV might have a causative role in the development of PCP cases in gay

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<sup>424</sup> Evidence of Dr. Davey, former Assistant National Director BTS, and Dr. Perrault, former National Director BTS, pp. 27197-27198.

<sup>425</sup> Ex. 122, Vol. 50, Tab 2 (Lewis et al., "Moral lessons; fatal cancer", *The Body Politic* October, 1981).

<sup>426</sup> Ex. 549, Vol. 124, Tab 1 (MMWR June 5, 1981).



men.<sup>427</sup> This was also postulated in the July 1981 *MMWR*, which reported on cases of KS and PCP in gay men in California and New York City. The report stated that it was uncertain if the "clustering" of both PCP and KS in gay men was related.<sup>428</sup>

289. In hopes of determining the cause of these infections, blood tests were performed on men experiencing these infections. A study in the December 10, 1981 *New England Journal of Medicine* (hereinafter referred to as "NEJM") reported on the results of immunologic testing, which revealed that the lymphocyte and T-cell counts of the PCP patients were depressed, while their humeral, or antibody-based, immunity reacted normally.<sup>429</sup>

290. By the end of 1981, scientists at the Centres for Disease Control in Atlanta (hereinafter referred to as "CDC") hypothesized that PCP and KS patients were suffering from a defect in their immune systems which curbed the body's natural ability to defend itself against cancer and pneumonia. What was originally hypothesized to be a new strain of PCP or KS was now considered to be the traditional PCP and KS affecting new populations with immune system difficulties.<sup>430</sup>

291. While it was evident by 1982 that some form of immune dysfunction made certain gay men vulnerable to these unusual diseases, what caused this immune suppression was a matter of great debate. The scientific community queried why, if underlying immune suppression was at the root of the appearance of opportunistic infections, the infections observed were so specific

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<sup>427</sup> *Ibid.*

<sup>428</sup> *Ex. 549, Vol. 124, Tab 2, p. 2 (MMWR July 3, 1981).*

<sup>429</sup> *Ex. 549, Vol. 124, Tab 6 (Masur et al., "An Outbreak of Community-Acquired Pneumocystis Carinii Pneumonia." *New England Journal of Medicine* December 10, 1981).*

<sup>430</sup> *Ex. 549, Vol. 124, Tab 7 (Siegal et al., "Severe Acquired Immunodeficiency in Male Homosexuals, Manifested by Chronic Perianal Ulcerative Herpes Simplex Lesions." *The New England Journal of Medicine* December 10, 1981).*



and apparently limited to PCP and KS when other conditions common in immune suppressed patients were not presenting themselves.<sup>431</sup>

292. The May 1982 *MMWR* reported cases of swollen lymph nodes in gay men which were "not attributable to previously identified causes". In the first study done on fifty-seven lymphadenopathy patients, it was noted that some exhibited abnormal T-helper cell to T-suppressor cell ratios. Studies on gay men with lymphadenopathy in Atlanta and San Francisco revealed the same reversed ratios. In light of reports of KS and opportunistic infections in the same population, researchers were concerned.<sup>432</sup>

293. Early in 1982, the CDC, Bureau of Epidemiology and the Laboratory Centre for Disease Control in Ottawa (hereinafter referred to as "LCDC") requested physicians to forward to them any information on cases of immune suppression in gay men.<sup>433</sup>

294. By June, 1982, the CDC defined AIDS as illness in a person who:

- 1) has either biopsy-proven KS or biopsy- or culture-proven life-threatening opportunistic infection;
- 2) is under age 60; and
- 3) has no history of either immunosuppressive underlying illness or immunosuppressive therapy.<sup>434</sup>

In retrospect, this CDC definition of AIDS, by its very nature limited the understanding of the disease and had an effect on the calculation of the actual number of AIDS cases. While epidemiologists tracking the course of AIDS received reports of cases of AIDS, many of these

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<sup>431</sup> Ex. 562, Tab 25, pp. 46 and 56 (July 19, 1983, *Transcript Blood Products Advisory Committee Meeting*).

<sup>432</sup> Ex. 549, Vol. 124, Tab 18, pp. 58-59 (*MMWR* May 21, 1982).

<sup>433</sup> Ex. 549, Vol. 124, Tab 14 (March 27, 1982 *Canadian Diseases Weekly Reports*).

<sup>434</sup> Ex. 549, Vol. 124, Tab 25 (*MMWR* June 11, 1982).



cases were not included in the official AIDS case statistics because they did not fit within the CDC definition.

5) Immune Deficiency Hypotheses

295. Following the first reports of unusual infections in gay men and continuing through to the discovery of HIV, a variety of theories were advanced to explain the etiology of AIDS. In the early days of the syndrome the number of AIDS cases in the United States doubled every six months. This trend did not necessarily indicate the presence of an infectious agent as it could, instead, denote group exposure to a toxic substance.<sup>435</sup> A virus was thought to be a probable cause during the outbreaks of phocomelia observed in babies from 1959-1961. Later, two researchers found the cause to be Thalidomide. Also, Reyes Syndrome, a severe complication of chicken pox or influenza, was initially thought to be virally induced but was eventually linked to aspirin use.<sup>436</sup> Accordingly, one had to consider and critically examine theories that were advanced to explain this new syndrome, including drugs, cytomegalovirus infection, antigenic or protein overload and co-factors.

(i) Drugs

296. When cases of KS and PCP were first observed in some gay men, researchers studying the phenomenon looked for a common link to explain the clustering of these illnesses, which were associated with host suppression.<sup>437</sup> Reports of opportunistic infections in IV drug

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<sup>435</sup> Evidence of Dr. Francis, *Epidemiologist*, p. 21584 [One such example is toxic shock syndrome].

Evidence of Dr. Clayton, *NAC AIDS Panel*, pp. 41806-41807; and

*Ex. 759, Vol. 165, Tab 1, p. 6 (November 1984 AIDS Centre News - World Federation of Hemophilia).*

<sup>436</sup> Evidence of Dr. Blake, *Province of Ontario Panel*, p. 18560.

<sup>437</sup> *Ex. 549, Vol. 124, Tab 4 (MMWR August 28, 1981).*



users suggested a possible relationship between drug use generally and the advent of these new illnesses. Such a relationship was strengthened by the knowledge that amyl nitrate, a street drug known as "poppers", was a popular drug used by gay men. There was noted a correlation between people who used poppers and those who contracted venereal disease. Therefore, it was postulated that there may also be a link between poppers and PCP and KS. The editorial in the December, 1981 *NEJM* suggested that drug use might be responsible for inducing this immune suppression:

So-called "recreational" drugs are one possibility. They are widely used in the large cities where most of these cases have occurred, and the only patients in the series reported in this issue who were not homosexual were drug users. Fashions in drug use change frequently, and experimentation with new agents is common. Perhaps one or more of these recreational drugs is an immunosuppressive agent.<sup>438</sup>

297. In another article published in this *NEJM* edition, Dr. Henry Masur, a senior investigator and Director of the National Institutes of Health (hereinafter referred to as "NIH")<sup>439</sup>, probed the issue of a link between drug use (amyl nitrate, heroin, methadone, alcohol and cocaine) and opportunistic infections.<sup>440</sup> Dr. Masur's observation that gay men, who were displaying signs of PCP and KS, did not seem to be spreading their condition to any of their immediate sexual contacts, lent support to the drug-use theory.<sup>441</sup>

298. In March, 1982, the CDC published a report on the epidemiological aspects of the outbreak of KS and opportunistic infections. A survey of 420 men who had attended STD clinics found that 86.4% of the gay men, as compared to 14% of the heterosexual men, had used

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<sup>438</sup> Ex. 549, Vol. 124, Tab 8, p. 29 (D.T. Durack, "Opportunistic Infections and Kaposi's Sarcoma in Homosexual Men." *The New England Journal of Medicine* December 10, 1981).

<sup>439</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22533; and Evidence of Dr. Mosley, Pediatrician, Hemophiliac Treater, p. 25824.

<sup>440</sup> Ex. 549, Vol. 124, Tab 6, p. 20 (Masur et al., "An Outbreak of Community-Acquired Pneumocystis Carinii Pneumonia", *The New England Journal of Medicine* December 10, 1981).

<sup>441</sup> *Ibid* at p. 20.



"poppers" within five years. The CDC continued its studies to see what role, if any, "poppers" had as a risk factor for the development of KS, PCP and immune suppression.<sup>442</sup>

299. In May, 1982, Dr. Michael Marmor of the Department of Environmental Medicine, New York Medical Centre and Columbia University, reported on the results of an investigation of twenty gay men with confirmed KS and forty control subjects. This study revealed that there was a significant association between KS and drug use including amyl nitrate, cocaine and amphetamines. Of all the drugs used, only amyl nitrate was associated with significantly elevated risk ratios. All patients with KS reported using amyl nitrite at least once. Marmor suggested that the epidemic of these conditions in gay men might have resulted from nitrite use and concluded:

The critical findings of the present study were that amyl nitrite exposure and sexual promiscuity were associated with development of Kaposi's sarcoma, as were histories of mononucleosis and sexually transmitted diseases.<sup>443</sup>

300. In the June 18, 1982 *MMWR* report on the "cluster" of cases of KS and PCP, the authors cited Marmor's study and noted that street drug use was common and could lead to immuno-suppression:

Exposure to some substance (rather than an infectious agent) may eventually lead to immunodeficiency among a subset of the homosexual male population that shares a particular style of life.<sup>444</sup>

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<sup>442</sup> Ex. 549, Vol. 124, Tab 22 ("The Syndrome of Kaposi's Sarcoma and Opportunistic Infections: An Epidemiologically Restricted Disorder of Immunoregulation" *Annals of Internal Medicine*, June, 1982); and

*Ibid*, Tab 26 (MMWR, July 18, 1982).

<sup>443</sup> Ex. 549, Vol. 124, Tab 17, p. 57 (Marmor et al., "Risk Factors for Kaposi's Sarcoma in Homosexual Men", *The Lancet* May 15, 1982).

<sup>444</sup> Ex. 549, Vol. 124, Tab 26 (MMWR, June 18, 1982).



301. The scientific journals throughout the summer of 1982 reported similar findings of "popper" and other drug use in association with this new syndrome.<sup>445</sup> In this regard, Dr. Arthur Levine of the National Cancer Institute (hereinafter referred to as "NCI") wrote in *Cancer Treatment Reports*:

It is of great interest that nitrites are the only drug the use of which has sharply increased in the US during the 1970's. Of interest is also the fact that the nonmedicinal-grade nitrites now in use were first manufactured in California and then shipped to New York City...

...a very extensive case-control will be required to sort out the relative contributions of nitrites and transmissible microbes: in fact, it may be impossible to identify specific risk factors.<sup>446</sup>

302. An article published in the September, 1982 *Journal of the American Medical Association* (hereinafter referred to as "JAMA") reported that it was unlikely that a virus (such as CMV, EBV or HPV) alone was responsible for inducing AIDS. Drugs such as marijuana and amyl nitrite were known to induce immune suppression. The studies on the effect of nitrite on the immune system undertaken by Dr. Marmor and Dr. Evan Hersh of M.D. Anderson were cited. James Goedert of the NCI was quoted as saying that the use of drugs, such as cocaine, amphetamines etc. increased the likelihood of disease development.<sup>447</sup>

303. By November 1982, the theory that "poppers" or drug use might directly cause immuno-suppression was waning in popularity. There were an increasing number of reports of

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<sup>445</sup> Ex. 549, Vol. 124, Tab 19, pp. 63-64 (Friedman-Kien et al., "Disseminated Kaposi's Sarcoma in Homosexual Men." Annals of Internal Medicine June, 1982);

Ex. 549, Vol. 124, Tab 8, p. 29 (D. Durack, "Opportunistic Infections and Kaposi's Sarcoma in Homosexual Men." New England Journal of Medicine December 10, 1981); and

Ex. 549, Vol. 124, Tab 26, p. 99 ("A Cluster of Kaposi's Sarcoma and Pneumocystis carinii Pneumonia among Homosexual Male Residents of Los Angeles and Orange Counties, California", MMWR June 18, 1982).

<sup>446</sup> Ex. 549, Vol. 124, Tab 24, p. 90 (A. Levine, "The Epidemic of Acquired Immune Dysfunction in Homosexual Men and Its Sequelae - Opportunistic Infections, Kaposi's Sarcoma, and Other Malignancies: An Update and Interpretation." Cancer Treatment Reports June, 1982).

<sup>447</sup> Ex. 549, Vol. 124, Tab 37, p. 132 (C. Macek, "Acquired immunodeficiency syndrome cause(s) still elusive." Journal of American Medical Association September 24, 1982).



AIDS in individuals who had never used these substances, which led researchers to conclude that it was likely not causative of the syndrome. Nonetheless, drug use, including the use of amyl nitrite, continued to be considered as a possible "co-factor", necessary for the development of full-blown AIDS.<sup>448</sup>

## (ii) Cytomegalovirus

304. In the early 1980s, the theory that this syndrome was caused by frequent and multiple infection with CMV, either through sexual transmission or frequent exposure to clotting factor, was also widely held. Many researchers believed that "a new agent" could not be responsible for the range of conditions found in such a small sub-group of people. CMV was known to be ubiquitous in the general population and when the first cases of AIDS among gay men were reported, it was hypothesized by some scientists that CMV caused this phenomenon in persons who were sexually promiscuous.

305. In the first *MMWR* report on the PCP cases in Los Angeles CMV was suggested as a possible etiologic agent in the development of the new syndrome for several reasons.<sup>449</sup> CMV exposure and infection were apparently rampant in the gay male community. All the patients with AIDS studied displayed CMV antibodies. In many cases they actually shed the CMV virus, which was an indication of an active and serious infection with CMV.<sup>450</sup> Finally,

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<sup>448</sup> Ex. 122, Vol. 50, Tab 4, p. 16 (*The Body Politic*, November 1982).

<sup>449</sup> Ex. 549, Vol. 124, Tab 1 (*MMWR*, June 5, 1981); and

*Evidence of Dr. Francis, Epidemiologist*, p. 21576.

<sup>450</sup> Ex. 549, Vol. 124, Tab 5 (K. Hymes et al., "Kaposi's Sarcoma in Homosexual Men - A Report of Eight Cases." *The Lancet* September 19, 1981);

Ex. 549, Vol. 124, Tab 9, p. 35 (M. Gottlieb et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men." *The New England Journal of Medicine* December 10, 1981); and

Ex. 549, Vol. 124, Tab 10, p. 38 (R.M. Du Bois et al., "Primary Pneumocystis Carinii and Cytomegalovirus Infections." *The Lancet* December 12, 1981).



it was well recognized that CMV produces an immunosuppressive effect in humans.<sup>451</sup> In fact, research on CMV and immune suppression had been undertaken long before the first AIDS cases emerged.<sup>452</sup>

306. In a December 12, 1981 *Lancet* editorial, the CMV link was reviewed in detail. Mice infected with CMV showed higher rates of mortality from fungal and bacterial infections. Moreover, analysis of T-cell ratios in CMV-infected patients showed a reversal of T-helper to T-suppressor ratios.<sup>453</sup> Studies had also demonstrated a link between CMV and KS. KS patients demonstrated an extremely high rate of CMV seropositivity (being 13 to 16 times greater than healthy men). Finally, CMV DNA presence had been suggested in KS cells. Moreover, it was hypothesized that KS was virally induced.<sup>454</sup>

307. Similarly, in the June 1982 edition of the *Annals of Internal Medicine*, Dr. Stephen Follansbee reported that in all of his patients there was evidence for either acute or preceding infection from CMV.<sup>455</sup> He noted that of the factors dominant in patients:

...all of whom were homosexual, only cytomegalovirus infection was consistently noted. In view of the known capacity of cytomegalovirus to depress various components of the immune reaction, it seems possible that repeated cytomegalovirus exposure or infection or both initiates a state of severe immunocompromise that in turn provides the necessary conditions for the emergence of opportunistic infections...<sup>456</sup>

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<sup>451</sup> Ex. 562, Tab 1 ("Immuno compromised Homosexuals", *The Lancet* December 12, 1981).

<sup>452</sup> *Ibid*, see *Lancet* footnotes, 7-17, p. 1325.

<sup>453</sup> Ex. 562, Tab 1, p. 1325 ("Immuno compromised Homosexuals", *The Lancet* December 12, 1981).

<sup>454</sup> *Ibid* at p. 1325.

<sup>455</sup> Ex. 549, Vol. 124, Tab 21, p. 79 (S. Follansbee et al., "An Outbreak of *Pneumocystis carinii* Pneumonia in Homosexual Men." *Annals of Medicine* June 1982).

<sup>456</sup> *Ibid* at p. 80.



308. Dr. Anthony Fauci concurred with Dr. Follansbee's view that CMV was a possible causative agent for the syndrome.<sup>457</sup> While Dr. Fauci also considered that CMV could simply be another opportunistic infection leaving the cause of the condition still unexplained, he noted that infection with and recent exposure to CMV and HSV were "strikingly predominant" and reported in his editorial:

Cytomegalovirus has been thought to be the primary causal agent in the induction of the immunosuppressed state (4), with subsequent infections or Kaposi's sarcoma resulting from the underlying immunosuppression originally caused by cytomegalovirus. This hypothesis is not unreasonable because cytomegalovirus can cause transient immunosuppression in normal hosts (7). The likelihood of frequent re-exposure and reinfections with cytomegalovirus among persons with a high degree of sexual promiscuity within a confined group could conceivably lead to a state of profound and apparently permanent immunosuppression directly related to recurrent viral infection, as opposed to the clinically insignificant degree and duration of immunosuppression usually seen in hosts with a single exposure.<sup>458</sup>

309. By July, 1982, the appearance of cases of AIDS in hemophiliacs who infused large and frequent doses of pooled concentrates, lent credence to the possibility that multiple infections with CMV might lead to the state of immuno suppression, which was now being called "AIDS."<sup>459</sup>

310. In the January, 1983, Dr. Jay Menitove, Director of the Blood Centre of South Eastern Wisconsin reported in the *NEJM*:

The proposed explanations for AIDS include infections (cytomegalovirus), drug use (inhaled nitrites), and exposure to foreign antigens (spermatozoa). Our data are consistent with the possibility that commercially prepared lyophilized factor

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<sup>457</sup> Dr. Fauci was described as a "legend" in relation to his work with immunologic disease. See evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22367.

<sup>458</sup> Ex. 549, Vol. 124, Tab 22, p. 83 (A. Fauci, "The Syndrome of Kaposi's Sarcoma and Opportunistic Infections: An Epidemiologically Restricted Disorder in Immunoregulation." *Annals of Medicine* June 1982).

<sup>459</sup> Ex. 553, Vol. 127, Tab 18, p. 78 (July 27, 1982 Open Meeting of the PHS Committee on Opportunistic Infections in Persons with Hemophilia).



VIII concentrates can induce an AIDS-like picture, but a large number of patients must be studied before a definite conclusion can be drawn.<sup>460</sup>

311. On May 4, 1983, the NIH held a meeting of the Interagency Technical Committee to discuss, in part, the issue of AIDS. The minutes show that Dr. Gerald Quinnan, head of the Virology Division of the FDA, highlighted the possible relationship between AIDS, CMV and EBV:

...Dr. Quinnan felt that CMV and EBV may be important in the etiology of AIDS. It was not possible to account for the high frequency of both infections simply as a result of immunosuppression, since reactivation of other herpes viruses was much less common. In other situations where reactivation follows immunosuppression, such as after bone marrow transplantation, herpes simplex virus reactivation occurs at least as often as CMV or EBV reactivation. There is a selective propensity for infections with CMV and EBV in AIDS patients.

Dr. Quinnan summarized by stating that it was possible that mixed infection with CMV and EBV would be the cause of AIDS. Chronic infection with these two viruses could be responsible for chronic elevation of serum interferon levels and the associated arrest in maturation of immune cells... It remains to be determined whether either of these viruses represent a new variant or whether there is a previously unrecognized interaction between the immune responses to EBV and CMV that would allow for establishment of chronic mixed infection.<sup>461</sup>

312. In July 19, 1983 at the American FDA, Blood Products Advisory Committee (hereinafter referred to as "BPAC") meeting in Washington to address the issue of AIDS in hemophiliacs, Dr. Quinnan reviewed current research on the etiology of AIDS, which suggested the possibility of a transmissible agent, albeit not a new one:

Dr. Quinnan suggested that AIDS is new in homosexual males, drug abusers, and other populations, but may not be caused by a new agent. It has been suggested that AIDS may be caused by infection with a virus. Among the

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<sup>460</sup> *Ex. 550, Vol. 125, Part I, Tab 15, p. 71 (J. Menitove et al., "T-Lymphocyte Subpopulations in Patients with Classic Hemophilia Treated with Cryoprecipitate and Lyophilized Concentrates." New England Journal of Medicine January 13, 1983).*

<sup>461</sup> *Ex. 555, Vol. 128, Part II, Tab 20, pp. 112-113 (Minutes of May 4, 1983 Interagency Technical Committee Meeting).*



viruses considered have been human T-cell leukaemia virus, parvovirus, papovaviruses, as well as agents such as cytomegalovirus (CMV) and Epstein Barr virus (EBV).<sup>462</sup>

313. The hypothesis that a mutation of CMV or another pre-existing virus was causing immuno-suppression was popular and led researchers to continue to study CMV. For example, in the August 1983 edition of the *Annals of Internal Medicine*, Dr. Gottlieb suggested that CMV could enter a cell and oncogenically transform it, allowing for an expression of dormant oncogenes.<sup>463</sup>

314. The theory that AIDS was caused by some mutation of a known virus or viruses, such as CMV, remained popular until the discovery of HIV. Since AIDS initially appeared to be limited to specific groups, many investigators considered that CMV, perhaps in combination with other infections led to a "breakdown of the patient's immune system". Following Montagnier and Gallo's discovery of HIV, CMV was paid little heed. Nevertheless, it was still considered to play a role in inducing full blown AIDS, and would later be cited as a possible "co-factor" in disease expression.<sup>464</sup>

### (iii) Antigenic Overload or "Insults" to the Immune System

315. Among Canadian scientists and hemophilia treaters throughout 1982 and 1983, the "antigenic overload" theory was the leading hypothesis on the cause of AIDS.<sup>465</sup> This was a theory that applied equally to explain the syndrome in hemophiliacs and gay men. The hypothesis of immune overload posited that AIDS could be caused by the repeated bombardment

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<sup>462</sup> Ex. 566, Vol. 138, Tab 4, p. 32 (July 19, 1983 FDA Blood Products Advisory Committee Summary Minutes).

<sup>463</sup> Ex. 551, Vol. 125, Pt. II (Gottlieb et al. "The Acquired Immune Deficiency Syndrome", *Annals of Internal Medicine*, August 1983).

<sup>464</sup> Evidence of Dr. Teitel, Medical Director of Hemophilia Ontario, pp. 34040-34041 and 33871-33872.

<sup>465</sup> Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31164 and 31444-31445.



of a large number of commonly known infectious agents such as CMV, EBV and HS on the immune system, causing it to break down.<sup>466</sup> Gay men were bombarded with common infectious agents regularly because of their sexual promiscuity. Similarly, hemophiliacs were regularly exposed to pooled concentrates and, consequently, to EBV, CMV, or other viruses, foreign proteins, and bacteria. It was postulated that this caused an "antigen overload" which overwhelmed the immune system and resulted in immune suppression:<sup>467</sup>

The main theory that we discussed at that time was the theory of immune suppression. Immune suppression that has been present in our patients for a long time, probably before -- and the possibility of either the immune suppression caused by the protein load -- the antigen load they were getting.

Either this opens them to opportunistic infection, or that in addition to this suppression there was another factor that made them act on these suppressed, or abnormal immune systems.

So this was the theory that was number one in our group, and this is why we were so eager to go ahead and to have another study going very, very early.<sup>468</sup>

The "overload" theory explained many discrepancies observed in the syndrome, such as the fact that blood transfusion recipients did not appear to be afflicted by the disease.

316. In the August, 1982 edition of *Science*, Drs. Spira and Haverkos of the CDC supported the view that recent reports of three cases in hemophiliacs had raised the possibility that an infectious agent could be transmitted by clotting factors. Dr. Haverkos noted that there was no evidence that it was transmitted to a transfusion recipient, as opposed to a severe hemophiliac:

Hemophiliacs require two or three injections of clotting factor per week and the material is prepared from the blood of many individual donors, which means

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<sup>466</sup> Evidence of Dr. Davey, former Assistant National Director BTS, pp. 26536-26537, 27303-27305, 29978; and

Evidence of Dr. Teitel, Medical Director of Hemophilia Ontario, pp. 34040-34041.

<sup>467</sup> Evidence of Dr. Davey, former Assistant National Director BTS, p. 27304.

<sup>468</sup> Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31444-31445.



that hemophiliacs' total exposure to foreign substances is much greater than that of patients who receive transfusions of whole blood.<sup>469</sup>

Dr. Thomas Spira, concurred and opined that recurrent antigenic stimulation could cause a "paralysis" of the immune system in hemophiliacs.<sup>470</sup>

317. In early 1983, scientists studying the new condition were chiefly concerned that hemophiliacs, as opposed to blood transfusion recipients, were at risk for developing AIDS, not necessarily because an infectious agent was transmitted when AHF was infused, but because of the repeated antigenic challenge:

It seemed to be consistent at the time with our thinking about homosexual transmission, that in the absence of knowledge that it was blood-borne, or that it was a virus that might be causing this, that at least repeated exposures to whatever it was might be the factor that determines progression to prodromal or on to AIDS stages.<sup>471</sup>

318. On January 4, 1983, the CDC convened a meeting with bloodbankers and other interested parties to discuss the possibility that AIDS could be transmitted by blood or blood products.<sup>472</sup> Dr. Louis Aledort, co-medical director of the NHF, and an internationally respected expert in hemophilia care, questioned the theory that AIDS was caused by a new agent and suggested that multiple infusions of concentrate might cause a patient to be a host for disease.<sup>473</sup>

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<sup>469</sup> Ex. 549, Vol. 124, Tab 31, p. 111 (Jean L. Marx, "New Disease Baffles Medical Community." *Science* August 13, 1982).

<sup>470</sup> *Ibid* at p. 112.

<sup>471</sup> *Evidence of Dr. Soskolne, Professor of Epidemiology in the Department of Public Health Sciences*, p. 24552.

<sup>472</sup> Ex. 554, Vol. 128, Part 1, Tab 2, pp. 2-23 (January 4, 1983 Minutes of CDC).

<sup>473</sup> Ex. 554, Vol. 128, Part 1, Tab 6, p. 64 (January 4, 1983 Cutter Laboratories Record of AIDS Meeting, Atlanta).



319. There was no certainty as to how or why only certain people's immune systems weren't functioning properly. In May 1983, Dr. Herst wrote in an *AIDS and Hemophilia Bulletin*:<sup>474</sup>

The exact nature of the disease mechanism in AIDS has not been established. One possibility is that it is caused by an infectious agent transmitted through body secretions and blood. The agent has not been isolated and there is no specific test for AIDS. Another theory is that repeated exposure to many different proteins (such as coagulation proteins in plasma from many donors or proteins in body secretions from many individuals) causes changes in the immune system.<sup>475</sup>

320. At the annual American Blood Resources Association annual conference for bloodbankers in June 1983, Dr. Aledort from Mount Sinai Medical Centre and Chair of the NHF MSAC, raised the question of whether transfusion could transmit an "agent" or whether repeated transfusions were necessary to induce a state of immune incompetence. He hypothesized that several factors were probably necessary to induce immunodeficiency, all of which must transpire before AIDS developed. He postulated that antigenic overload was causing immune suppression in the "host", which would explain why there were cases of AIDS amongst hemophiliacs as opposed to the millions of blood transfusion patients who had failed to manifest the syndrome.<sup>476</sup>

321. The "antigen overload" theory remained current into 1984. In 1984, Dr. Russell Jaffe of the CDC presented an abstract challenging the single agent theory at the annual World Federation of Hemophilia (hereinafter referred to as "WFH") Conference in Rio de Janeiro. He suggested that prior immunocompromise would pre-dispose someone to subsequent infection. This compromise might arise from "chronic immune system overstimulation or suppression by toxic metal accumulation, intestinal parasites, reactive foods/chemicals, stress, recreational

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<sup>474</sup> Ex. 754, Vol. 160, Tab 5, p. 9 (Roslyn Herst, "Hemophilia and Acquired Immune Deficiency Syndrome (AIDS)", May 1983).

<sup>475</sup> *Ibid.*

<sup>476</sup> Ex. 754, Vol. 160, Tab 36, p. 149 (June 7-9, 1983 Trip Report prepared by Dr. Naylor).



chemical use, yeast infection, or foreign protein.<sup>477</sup> Dr. Jaffe also suggested that how this immunocompromise manifested itself could vary:

AIDS may represent an aspect of a new syndrome (disorders of Immunoregulation) which variably express as impaired fertility, autoimmune disease, certain rheumatoid disorders, chronic infections, cancer risk, immunodependent atherosclerosis, or acquired immunodeficiency, depending upon the contingent variables.<sup>478</sup>

322. Both the CMV and the antigenic overload theories suggested that a person had to be exposed to numerous agents, in combination, which resulted in a breakdown of the immune system. This interrelationship between massive overload and re-infection with numerous immuno-suppressive viruses explained why hemophiliacs were hosting the syndrome while transfusion recipients, for the most part, were not.<sup>479</sup>

#### (iv) The Infectious Agent Theory

323. While many scientists and physicians believed that the theories canvassed above were valid, other researchers contended that the similarity in the epidemiology of AIDS and Hepatitis B demonstrated that the syndrome was caused by a blood-borne, transmissible agent.<sup>480</sup> They hypothesized that a new infectious agent was responsible for the breakdown of the immune system observed in certain groups.

324. Some researchers were not entirely convinced of "the fit" of the Hepatitis B model. While groups generally at risk for Hepatitis B, such as hemophiliacs, IV drug users and gay men were developing the syndrome, the appearance of AIDS in other groups, namely

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<sup>477</sup> Ex. 759, Vol. 165, Tab 1, p. 6 (AIDS Centre News - World Federation of Hemophilia - Russell Jaffee "Complimentary Therapy in AIDS: Observation of the Phenomenon").

<sup>478</sup> *Ibid* at p. 6.

<sup>479</sup> Ex. 754, Vol. 160, Tab 36, p. 149 (June 7-9, 1983 Trip Report prepared by Dr. Naylor).

<sup>480</sup> Evidence of Dr. Francis, Epidemiologist, pp. 21559-21560.



Haitians, remained a mystery. Moreover, there were differences in the manner in which Hepatitis B and AIDS behaved, whatever its cause. AIDS was not running rampant through dialysis units, as Hepatitis B had<sup>481</sup>, nor was AIDS showing up in sickle cell and thalassaemia patients, despite both groups sharing a history of exposure to blood as part of their treatment.<sup>482</sup> Furthermore, in 1983, epidemiologists were not seeing an explosion of this disease among healthcare workers, as had been the case with Hepatitis B.<sup>483</sup> Many sexual partners of AIDS patients had not developed AIDS, nor were they demonstrating any immune abnormalities.<sup>484</sup> Thus, a number of the groups traditionally at risk for a blood-borne pathogen were not exhibiting the disease and certain "risk" groups for AIDS, such as Haitians, did not fit into any of the models.<sup>485</sup>

325. Therefore, the general consensus among the "single agent" theorists was that the putative agent was not highly infectious and was by no means as infectious as the Hepatitis B virus. In a November 1982 article, Dr. Lewis, a Professor of Surgery and Microbiology at University of Toronto, reported:

More significantly, the number of cases of AIDS reported has not risen dramatically over the past year -- despite the far greater medical and community awareness of the disease. During the past year the number of cases reported in gay men has risen from about thirty a month to about sixty, but this still represents a relatively modest rate of increase considering the vastly increased awareness on the part of physicians and gay men themselves. Even Dr. James Curran of the CDC, Atlanta has said that "it is safe to say that the AIDS

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<sup>481</sup> Evidence of Dr. Davey, former Assistant National Director BTS, pp. 27226-27228; and

Ex. 553, Vol. 127, Tab 26, p.108 (October 2, 1982 Minutes of the Meeting of the NHF Medical and Scientific Advisory Council).

<sup>482</sup> *Ibid.*

<sup>483</sup> Evidence of Dr. Francis, Epidemiologist, p. 22225.

<sup>484</sup> Ex. 562, Tab 34 (Kreiss, Kasper et al., "Nontransmission of T-Cell Subset Abnormalities from Hemophiliacs to Their Spouses." Journal of American Medical Association March 16, 1984).

<sup>485</sup> Evidence of Dr. Francis, Epidemiologist, pp. 21609-21610; and

Evidence of Dr. McSheffrey, Saskatoon Centre Medical Director, p. 8573.



syndrome is not readily transmitted, it is not an explosive disease like influenza." Curran believes that the number of cases reported will continue to rise at a steady but slow rate for some time.<sup>486</sup>

326. This profile of the disease was shared by many researchers, including Dr. Francis. In a September 1983 article, Dr. Francis and colleagues wrote:

Most researchers suspect that AIDS may be caused, at least in part, by an infectious agent (3). Such an agent would presumably be transmitted only with great difficulty, and in the case of intravenous drug abusers and hemophiliacs it could perhaps be transmitted by blood or blood products.<sup>487</sup>

327. The infectious agent theory was apparently inconsistent with another fact. In 1983 West Germany had the highest concentration utilization rate in the world as a result of their intense prophylaxis program. This required exposure to vast amounts of pooled American source concentrate on a daily basis. If the disease was spread like Hepatitis B through concentrate use, it was mysterious why hemophiliacs from West Germany reported no cases of AIDS.<sup>488</sup>

328. While there were reported cases of AIDS in a few hemophiliacs, there was no certainty that the syndromes causing the immune irregularity observed in gay men and hemophiliacs was identical. The immune abnormalities were different. There were demographic differences between the reported cases of AIDS in hemophiliacs and gay men. Hemophiliacs were not displaying KS, an identifiable feature and hallmark of the syndrome.<sup>489</sup>

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<sup>486</sup> Ex. 122, Vol. 50, Tab 4, p. 16 (The Body Politic November, 1982, Dr. Bill Lewis).

<sup>487</sup> Ex. 551, Vol. 125, Part II, Tab 33, p. 114 (M. Essex et al., "Antibodies to Human T-Cell Leukaemia Virus Membrane Antigens (HTLV-MA) in Hemophiliacs", Science September 9, 1983).

<sup>488</sup> Evidence of Dr. Davey, former Assistant National Director BTS, pp. 26539-26540; and

Ex. 554, Vol. 128, Part I, Tab 24, p. 148 (January 17, 1983 Memo of National Hemophilia Foundation/Industry Strategy Meeting).

<sup>489</sup> Ex. 947, Vol. 273, Tab 6, p. 11-12 (Acquired Immune Deficiency Syndrome Eds: Selikoff & Stierstein & Hirschman eds - Annals of New York Academy of Sciences - Vol. 437, 1984).



329. Dr. Tsoukas demonstrated that a large proportion of the severe hemophiliacs who received high doses of concentrate displayed an inverse ratio between the T4 and T8 cells - that is, the T4 cells were normal, while the T8 cells were abnormally high. By contrast, in gay men with AIDS all lymphocyte numbers were depressed.<sup>490</sup> Higher immunologic abnormalities were reported in hemophiliacs using concentrates than cryoprecipitates.<sup>491</sup> In some cases the T-cells were normal while in others the numbers decreased. These results were "distinctly different quantitatively from those that had developed AIDS..."<sup>492</sup>

330. Many researchers hypothesized that the inverse T4/T8 ratio being observed was evidence of "immune augmentation". Therefore, rather than being an indicator that a hemophiliac was in a prodromal stage to AIDS, such T-cell changes meant that they were successfully resisting a multitude of infectious agents to which they had been exposed through concentrate use.<sup>493</sup> This led many physicians familiar with hemophiliac disorders to theorize that the immune suppression in hemophiliacs might be of a different order and cause than that found in cases of gay men with AIDS.<sup>494</sup>

331. In 1983, there were other observations inconsistent with the theory that AIDS could be transmitted by clotting factor. Many healthy hemophiliacs had infused the same lots

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<sup>490</sup> Ex. 549, Vol. 124, Tab 6 (Henry Masur et al., "An Outbreak of Community Acquired Pneumocystis Carinii Pneumonia", December 10, 1981).

<sup>491</sup> Ex. 752, Vol. 159, Pt. 1, Tab 11.

<sup>492</sup> Evidence of Dr. Tsoukas, Montreal General Hospital, pp. 39715-39717.

<sup>493</sup> Ex. 553, Vol. 127, Tab 20, p. 89 (Glenn F. Pierce, "The Risk of Acquired Immune Deficiency Syndrome: A Patient's Perspective." Hemophilia Notes Summer, 1983);

Ex. 754, Vol. 160, Tab 15, p. 46 (May 13, 1983 Minutes of National MSAC Meeting);

Evidence of Dr. Tsoukas, Montreal General Hospital, pp. 39656-39657; and

Evidence of Dr. Grawe, Clinical Professor, Medicine Pathology, University of British Columbia, pp. 33071-33072.

<sup>494</sup> Evidence of Dr. Strawczynski, Montreal Children's Hospital, pp. 31160- 31164.



of concentrates as hemophiliacs who had developed AIDS.<sup>495</sup> This supported the theory that AIDS was the result of an antigen overload. Thus, it was thought that exposure to concentrates themselves, as opposed to a transmissible agent present in these concentrates, was responsible for the small number of cases of AIDS seen in hemophiliacs.<sup>496</sup>

332. Another fact at odds with the infectious disease theory was that there were some cases of AIDS reported in hemophiliacs but a corresponding absence of cases in transfusion recipients:

At a spring conference held by the American Blood Commission, it was pointed out that if AIDS were transmitted through blood, the incidence of the disease would increase among transfusion recipients in areas designated as "hot spots" by the CDC. No such increase has occurred.<sup>497</sup>

333. The search for a new infectious agent led some members of the scientific community to postulate that a virus discovered in 1980 by Dr. Gallo of the CDC was causing AIDS. HTLV-1 (Human T-cell Leukaemia virus) was the first retrovirus found in humans.<sup>498</sup> While the virus was known to be attracted to lymphocytes, initially it was unknown what disease this retrovirus caused. In the wake of AIDS reports, Dr. Gallo mistakenly asserted that the

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<sup>495</sup> Ex. 566, Vol. 138, Tab 4, pp. 33-34 (July 19, 1983 FDA Blood Products Advisory Committee Summary Minutes).

<sup>496</sup> Ex. 554, Vol. 128, Part I, Tab 6, p. 64 (January 6, 1983 Internal Cutter Memo from John Hink to Dr. K. Fischer).

<sup>497</sup> Ex. 555, Vol. 128, Part II, Tab 16, p. 92 ("Hemophilia Letter", Summer, 1983, Vol. 5, No. 1).

<sup>498</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22889-22890; and

Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41652 and 41828.



HTLV-1 virus was the cause of AIDS.<sup>499</sup> (In fact, HTLV-1 was later identified as a virus which caused leukaemia.)

334. In the 1983 May *Science* edition, scientists from Dr. Montagnier's Pasteur Institute in Paris reported on the isolation of a distinct T-lymphotropic retrovirus from a patient at risk for AIDS. This was distinct from the HTLV-I virus discovered by Dr. Gallo in 1980 and was called Lymphadenopathy Associated Virus (hereinafter referred to as "LAV"). At this time, this virus (later identified as HIV) could not be conclusively linked or shown to be causative of AIDS.<sup>500</sup>

335. The April 1984 announcement of the "discovery" of the virus causing of AIDS by U.S. Secretary of Health Margaret Heckler was heralded by the media as a great breakthrough. It was announced that Dr. Gallo's team had discovered another human retrovirus, called HTLV-III, which highly correlated with AIDS. Despite the stated optimism that a cure was in sight, it was still unclear whether Dr. Gallo's new virus was, indeed, the cause of AIDS. While Dr. Gallo had shown a high incidence of specific antibodies to HTLV-III in patients with AIDS and pre-AIDS, there were concerns that this virus could simply turn out to be another opportunistic infection.<sup>501</sup>

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<sup>499</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22341;

Ex. 550, Vol. 125, Part I, Tab 50, pp. 174-175 (M. Essex et al., "Antibodies to Cell Membrane Antigens Associated with Human T-Cell Leukaemia Virus in Patients with AIDS." *Science* May 20, 1983); and

Ex. 550, Vol. 125, Part I, Tab 53 (Brian D. Johnson, "A vital clue to AIDS." *Macleans*, May 23 1983).

<sup>500</sup> Ex. 550, Vol. 125, Part I, Tab 52, p. 181 (F. Barre-Sinoussi et al., "Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)." *Science* May 20, 1983).

<sup>501</sup> Ex. 552, Vol. 126, Tab 37, pp. 139-140 (M. G. Sarnagadharan, "Antibodies Reactive with Human T-Lymphotropic Retroviruses (HTLV-III) in the Serum of Patients with AIDS." *Science* May 4, 1984).



(v) Co-Factors

336. In August, 1983, the results of a U.S. national epidemiologic case contact study were published. Dr. Jaffe and others at the CDC found that the highest correlation between development of AIDS and risk factors involved numbers of partners, exposure to feces, syphilis and hepatitis infection, enteric parasites and the use of street drugs.<sup>502</sup> While they hypothesised that the available evidence could support the theory of a blood-borne agent, they reported:

Although the number of sexual partners seems to be the most important risk factor, we cannot exclude the possibility that other highly correlated variables, such as illicit drug use, play some role in the development of these illnesses.<sup>503</sup>

337. Even after the announcement of the discovery of the virus in 1984, the belief that co-factors must be present before AIDS could develop was shared by many experts.<sup>504</sup> In July 1984 Dr. Gill of the LCDC firmly believed that there was more to AIDS than mere infection with the newly discovered virus.<sup>505</sup>

338. Well into 1987 (and indeed today) many scientists continued to speculate that co-factors played a role in the development of AIDS in sero positive individuals<sup>506</sup>. However, little long term research had been done to determine possible roles that nitrite use, co-infection with other viruses or repeated antigenic challenge might play in causing AIDS.<sup>507</sup>

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<sup>502</sup> Ex. 551, Vol. 125, Part II, Tab 9, p. 35 (H. Jaffe et al., "National Case-Control Study of Kaposi's Sarcoma and Pneumocystis Carinii Pneumonia in Homosexual Men: Part 1, Epidemiologic Results." *Annals of Internal Medicine* August 1983).

<sup>503</sup> *Ibid* at p. 40.

<sup>504</sup> Evidence of Dr. Sheppard, Head Section of Medical Oncology Division of Hematology/Oncology, The Toronto Hospital General and Western Divisions Hospital Branches, pp. 25252-25253.

<sup>505</sup> Evidence of Dr. Gill, Director of CRCS National Reference Laboratory, p. 42075.

<sup>506</sup> Ex. 562, Tab 37, 1359 (Donald Francis et al., "The Prevention of Acquired Immune Deficiency Syndrome in the United States." *Journal of American Medical Association* March, 1987, Vol. 257, No. 10).

<sup>507</sup> *Ibid* at p. 1359.



6) The Problem of the Latency Period Versus a Continuum of Symptom Expression

339. A complete understanding of a disease can only be gained through observation of its natural history. Absent an appreciation of the lengthy incubation period between infection and symptom display, a clear understanding of the nature of AIDS was not possible until late in the epidemic. As stated above, while it was understood that there was a latency period between exposure to an infectious agent and the development of symptoms, in 1980 there was no disease known to infect man in which the latency period was of great length; the longest viral latency periods known was that of the Hepatitis B infection, which could take as long as one to three months after infection before the manifestation of symptoms.<sup>508</sup>

340. What has become known as the "California baby case" was a first indication that, if this was a case of AIDS and if AIDS was due to a transmissible agent, the latency period could range from months to perhaps two years between exposure to the agent and illness.<sup>509</sup>

341. The December 10, 1982 *MMWR* reported a *possible* transfusion-associated case of AIDS in an infant in California, who received a transfusion of blood from a donor who was healthy at the time of donation, but who had developed symptoms of AIDS eight months later. The CDC reported:

If the platelet transfusion contained an etiologic agent for AIDS, one must assume that the agent can be present in the blood of a donor before onset of symptomatic illness and that the incubation period for such illness can be relatively long.<sup>510</sup>

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<sup>508</sup> *Evidence of Dr. Macpherson, former Medical Director of Health, City of Toronto, pp. 3497-3498.*

<sup>509</sup> *Ex. 550, Vol. 125, Part 1, Tab 1, pp. 1-2 (A. J. Pinching, "The Acquired Immune Deficiency Syndrome (AIDS)." The Bulletin 1983); and*

*Ex. 550, Vol. 125, Part 1, Tab 2, p. 4 ("Canadian Red Cross: AIDS A Challenge to Help Health Care Professionals").*

<sup>510</sup> *Ex. 549, Vol. 124, Tab 43, p. 156 (MMWR, December 10, 1982).*



A further discussion regarding this case can be found in part 7 of this Section "The Risk of Acquiring AIDS Through Blood Product Use or Transfusion".

342. The assumption that a latency period in AIDS might range from a number of months to two years evolved and was shared by scientists, and bloodbankers including the CRCS. Assessments of the risk of blood transfusion or use of blood products were based on an understanding that the latency period was, at most, a "lengthy two years". However, researchers had no appreciation that the undiscovered AIDS agent, HIV, could have the extremely long incubation period before manifestation of symptoms of ten years or more.<sup>511</sup>

343. Scientists attempted to develop a model of the syndrome encompassing three phases. The first was a symptom-free latency period of up to two years. This was followed by a prodromal phase of general malaise, lymphadenopathy and fever. However, it was far from certain whether the lymphadenopathy phase constituted a prodromal state:<sup>512</sup> that is, whether those with lymphadenopathy would, undoubtedly, go on to develop AIDS. The third phase was full-blown AIDS characterized by opportunistic infections, KS or PCP. It was postulated that only some patients would actually progress to full-blown AIDS.<sup>513</sup>

344. Some researchers hypothesized that there was a spectrum of clinical illnesses ranging from immune irregularity and lymphadenopathy to opportunistic infections such as KS and PCP. This is reflected in a June 1982 report by Dr. Arthur Levine of the NCI on the course of the illness now known as AIDS:

It is now clear that this new syndrome reflects a broad spectrum of events, beginning with an asymptomatic acquired immune abnormality. In a small subset of the affected population, this abnormality may eventuate in autoimmune phenomena, but in most cases, the abnormality is an asymptomatic immune deficiency. Further along the spectrum is a prodromal syndrome with fever of unknown origin, diarrhea, weight loss, malaise, thrush, and

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<sup>511</sup> *Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22514-22516.*

<sup>512</sup> *Ex. 562, Tab 25, p. 181 (July 19, 1983 Survey of Blood Products Advisory Committee meeting).*

<sup>513</sup> *Ibid.*



wasting....The most threatening end of the spectrum involves opportunistic infections and/or KS, and once any serious opportunistic infection has occurred, the course of these patients has been inexorably progressive (5-7). The percentage of patients in whom the more benign events in this spectrum will lead to the more serious events is uncertain.<sup>514</sup>

345. The CDC scientists were somewhat more reticent. Dr. Thomas Spira said that those at the CDC did not know whether lymphadenopathy was a prodrome or a milder manifestation of the severe disease. They were, however, concerned that these conditions were related.<sup>515</sup>

346. By September 1982 the CDC had re-worked its definition of "AIDS". It was now defined as a condition, but the definition did not reflect the broad spectrum of illnesses which could present in a case of AIDS.<sup>516</sup>

...at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease. Such diseases include KS, PCP, and OOI. Diagnoses are considered to fit the case definition only if based on sufficiently reliable methods (generally histology or culture)...

...However, this case definition may not include the full spectrum of AIDS manifestations, which may range from absence of symptoms (despite laboratory evidence of immune deficiency) to non-specific symptoms (e.g., fever, weight loss, generalized persistent lymphadenopathy)(4) to specific diseases that are insufficiently predictive of cellular immunodeficiency to be included in incidence monitoring (e.g., tuberculosis, oral candidiasis, herpes zoster) to malignant neoplasms that cause, as well as result from, immunodeficiency.<sup>517</sup>

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<sup>514</sup> Ex. 549, Vol. 124, Tab 24, p. 91 (A. Levine, "The Epidemic of Acquired Immune Dysfunction in Homosexual Men and its Sequelae - Opportunistic Infections, Kaposi's Sarcoma, and Other Malignancies: An Update and Interpretation." Cancer Treatment Reports June 6, 1982).

<sup>515</sup> Ex. 549, Vol. 124, Tab 31, p. 112 (J. L. Marx, "New Disease Baffles Medical Community." Science August 13, 1982).

<sup>516</sup> Vol. 125, Part II, Ex. 551, Tab 67, p. 240 (Terry Murray, "AIDS has hit 20,000 patients, minimum." The Medical Post).

<sup>517</sup> Ex. 549, Vol. 124, Tab 36, pp. 126-127 (MMWR, September 24, 1982).



347. Initially, evidence of cellular abnormalities and lymphadenopathy led some researchers to hypothesize that these lesser "symptoms" could be a prodrome to AIDS, which would eventually progress to full clinical illness.<sup>518</sup> However, in the latter half of 1983, after an opportunity to observe and follow people with lymphadenopathy for over two years, some scientists favoured the explanation that this state was a milder manifestation of AIDS. In a 1983 *NEJM* editorial, Dr. James Curran noted that while the strict application of the CDC surveillance definition of AIDS had been useful for detecting disease patterns, it could lead to an underestimation of the size and severity of the problem since it did not include those milder manifestations.<sup>519</sup>

348. In a June, 1983 editorial by Dr. Ronald Miller and Dr. Joseph Bove, the problems encountered in taking action in the absence of such knowledge were discussed:

The ability to make any intelligent decision and to evaluate its effect is complicated by the long (approximate 1 year) latency period. Therefore, decisions that are made now cannot be assessed for at least 1 year.<sup>520</sup>

349. During 1983, the term "AIDS-related complex" (hereinafter referred to as "ARC") was in common usage. It replaced "pre-AIDS" or "AIDS prodrome" as the term to describe the condition of those persons with persistent lymphadenopathy who did not appear to be progressing to AIDS.<sup>521</sup> Because patients with AIDS who underwent immunological testing demonstrated some immune dysfunction or immune abnormalities and most of these people did not seem to progress to "full-blown AIDS", it was hypothesized that certain individuals infected with HTLV-

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<sup>518</sup> *Ex. 551, Vol. 125, Part II, Tab 8, p. 29 (Gottlieb et al., "The Acquired Immunodeficiency Syndrome." Annals of Internal Medicine August 1983).*

<sup>519</sup> *Ex. 551, Vol. 125, Part II, Tab 27, p. 96 (James W. Curran, "AIDS - Two Years Later." The New England Journal of Medicine September 8, 1983).*

<sup>520</sup> *Ex. 550, Vol. 125, Part I, Tab 57, p. 193 (Bove et al., "Acquired Immunodeficiency Syndrome (AIDS) and Blood Products." The Journal of Anesthesiology June 1983).*

<sup>521</sup> *Ex. 551, Vol. 125, Pt. II, Tab 67, p. 241 (Terry Murray "AIDS has at least 20,000 patients, minimum". The Medical Post).*



III would only develop ARC".<sup>522</sup> AIDS-related complex was defined as a state of mild illness, which might be chronic in nature or last for a finite period of time. Researchers postulated that co-factors had to be present in a person before that individual would develop full-blown AIDS.<sup>523</sup> This theory explained why, out of the millions of transfusions given in the United States since the advent of the epidemic, very few AIDS cases had shown up in transfusion recipients. It further explained why the majority of people who may have been exposed to the virus apparently did not develop AIDS. By all appearances, some six or seven years into the American AIDS epidemic, the risk of contracting AIDS from blood transfusion was extremely low.<sup>524</sup>

350. In the April 1984 edition of "*Hemophilia Bulletin*" Dr. Kasper described doctors' "cautious optimism":

Although we cannot diagnose this complex with certainty, we think a few patients have it, some of them for years, without life-threatening illnesses. We keep close surveillance over these patients; as a group, they are not getting any worse. We are cautiously optimistic.<sup>525</sup>

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<sup>522</sup> Evidence of Dr. Lavigne, Epidemiologist, pp. 12739-12740;

Ex. 756, Vol. 162, Tab 31, p. 115 (March 5, 1984 Letter from Mr. F. Schnabel to Dr. P de Graaf with attachment);

Ex. 557, Vol. 130, Tab 33, p. 192 (August 1-2, 1985 Conference Report: "Guide to Public Health Practice: HTLV-III Antibody Testing and Community Approaches"); and

Evidence of Dr. Johnston, former Director of Division of Epidemiology, Ministry of Health, B.C., p. 4333.

<sup>523</sup> Ex. 558, Vol. 131, Part I, Tab 4, p. 47 (Epidemiologic Reviews, "Epidemiology of the Acquired Immunodeficiency Syndrome (AIDS)." undated), and

Ex. 557, Vol. 130, Tab 22 ("Stabilization of the Incidence of AIDS in Hemophilia Reported." Hemophilia Information Exchange May 17, 1985).

<sup>524</sup> Ex. 557, Vol. 130, Tab 6, p. 24 (DHHS Pamphlet: "Information for Individuals About AIDS and the Antibody Blood Test", dated February 14, 1985).

<sup>525</sup> Ex. 756, Vol. 162, Tab 53 (Hemophilia Bulletin, April 1984).



351. By late 1984, the latency period before the development of AIDS was thought to be between two to four years. The number of cases of AIDS was minimal, relative to the number of blood donations and the amount of pooled plasma concentrates used by hemophiliacs.<sup>526</sup> Hemophilia treaters were aware of how many hemophiliacs had tested antibody positive, however, it was understood that most of these people would stay healthy and not go on to develop AIDS. During the presentation at the December 10, 1984 Consensus Conference on heat-treated concentrates, (discussed fully in the Heat Treatment section) Dr. Card, the new Chair of CHS MSAC, acknowledged that there was a risk of developing AIDS through exposure to factor concentrates. He estimated the usual latency period was between twelve to twenty-four months and opined that:

...it is reassuring to note that a large proportion of hemophiliacs who have converted to HTLV-III positivity have not developed AIDS. Thus it may be that less than 1 in 100 of exposed severe hemophiliacs will develop AIDS. Indeed, it is very possible that the majority of multiply-treated hemophiliacs have already developed immunity.<sup>527</sup>

## 7) The Risk of Acquiring AIDS Through Blood Product Use or Transfusion

352. It was traditionally recognized that transfusion of blood or plasma derivatives could subject a patient to a variety of risks. Accordingly, clinical judgment had to be exercised by the physician to weigh the attendant risk of treatment against the benefit of the procedure.<sup>528</sup>

353. The best estimate which bloodbankers had in 1983 as to the general risks of transfusion came from a study by Dr. Paul Schmidt who, from 1977 to 1980, reviewed reported cases of death due to transfusion complications. He estimated that approximately one in 200,000

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<sup>526</sup> Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41704-41709.

<sup>527</sup> Ex. 759, Vol. 165, Tab 52, p. 181 (Dr. Card, "Heat-Treated Factor VIII Concentrates: Medical Views and Implementation Strategy." December 10, 1984).

<sup>528</sup> Ex. 67, Vol. 30, Tab 1 (CRCS 1980 "Clinical Guide to Transfusion: Products and Practices").



patients who were transfused died as a result of complications related directly to the therapy. Some of the known historical risks and recognized complications of blood transfusions included allergic and anaphylactic reactions due to the incompatibility of blood types. Dr. Schmidt reported that blood type incompatibilities occurred in approximately one in 6,000 cases, a small proportion of which were fatal. Dr. Schmidt estimated that, at the time of his study, serious infections associated with platelet transfusions occurred in the order of one in 4,000 cases.<sup>529</sup>

(i) **Risk of AIDS in Hemophiliacs**

354. The first indication that patients using blood products might be at risk for acquiring unusual opportunistic infections was reported to the scientific community and public in the July 1982 *MMWR* documenting three cases of hemophiliacs in the United States who had developed this syndrome.<sup>530</sup> A Public Health Service Advisory Committee (including representatives from the CDC, FDA, NIH, NHF, AmCross, and the National Gay Task Force (hereinafter referred to as "NGTF")) met to consider the implications of these reports on July 27, 1982.<sup>531</sup> It recommended that an active surveillance system be developed to determine if "other suspicious cases of AIDS are occurring in hemophiliac patients." The Committee concluded that the NHF and the NGTF should continue to have broad input into discussions of the AIDS problem.<sup>532</sup>

355. Following this meeting, the NHF's Chapter Advisory stated that the CDC was assessing whether there was a link between the three published cases and the new

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<sup>529</sup> *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 30893-30894.*

<sup>530</sup> *Ex. 549, Vol. 124, Tab 29 (MMWR, July 16, 1982).*

<sup>531</sup> *Ibid, Tab 29; and*

*Ex. 553, Vol. 127, Tab 18, p. 77 (July 27, 1982 Minutes of the Open Meeting of the PHS Committee on Opportunistic Infections).*

<sup>532</sup> *Ibid at p. 79.*



immunodeficiency condition being observed in gay men, Haitians and IV drug users. The NHF asserted that:

At this time there is no indication that blood products are involved although CDC is investigating if the disease agent may be a virus transmitted similarly to the hepatitis virus by blood products.<sup>533</sup>

The Advisory concluded that the risk of contracting an immuno suppressive agent was minimal and noted that the CDC was not recommending any change in blood product use.

356. Following the July 1982 *MMWR*, the CDC prepared briefing notes on "Questions and Answers on AIDS", which postulated that hemophiliacs might be at a higher risk for developing AIDS than the general population.<sup>534</sup> CDC staffers, Dr. James Maynard and Dr. Francis, who were part of a team investigating the opportunistic infection cases, advocated rapid investigation into whether blood products could transmit AIDS:

Recommendations are needed regarding use of blood and blood products as, in the absence of solid recommendations, lives could be lost either because of continued use of these products or because of unfounded fear and non-use. Without additional information, however, recommendations will be difficult to make.<sup>535</sup>

357. Even before the advent of AIDS, it was known that hemophiliacs exposed to concentrates of pooled blood components had immune irregularities and suppression. This was confirmed in Dr. Tsoukas' studies.<sup>536</sup> The CDC had conducted a study of 230 hemophiliacs,

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<sup>533</sup> Ex. 553, Vol. 127, Tab 13 (July 19, 1982 *Hemophilia News Notes Chapter Advisory #2*).

<sup>534</sup> Ex. 553, Vol. 127, Tab 33, p. 121 (November 1982 *Questions and Answers on AIDS*, Department of Health and Human CDC Services).

<sup>535</sup> Ex. 553, Vol. 127, Tab 5 (July 8, 1982 *Potential Transmission of KS/OI By Blood Or Blood Products*).

<sup>536</sup> Evidence of Dr. Tsoukas, *Montreal General Hospital*, pp. 39722-39724;

Ex. 947, Vol. 273, Tab 7 (Tsoukas, Chris, D.M.P. Thomson and Kerry Phelan, "Leukocyte Activation in Classic Hemophilia Resulting From Factor VIII Concentrate Infusion", published circa 1985);

Ex. 847, Vol. 187, Tab 1 (CDWR, dated December 11, 1982); and



who were followed from 1975 to 1983. In 1975, their lymphocyte counts were normal. However, a gradual decrease in lymphocyte numbers over the course of eight years was observed, resulting in lymphocyte numbers in hemophiliacs' 1000 counts lower than in the normal population.<sup>537</sup> However, the meaning of this observation was unclear. Researchers, such as Dr. Tsoukas, were adamant that such findings not lead to panic, as it was "far too early" to determine its significance in relation to AIDS.<sup>538</sup> This sentiment was shared by Dr. Evatt of the CDC in 1983:

... although not only are we finding those abnormalities in hemophiliacs, a lot of other investigators are finding those. They probably represent nonspecific finding (sic) which could be as much due to chronic infections with other viruses as well as any relationship to AIDS, and I think it is way too early to make any decision on whether or not that has anything to do with AIDS.<sup>539</sup>

358. On August 6, 1982, the Canadian HPB produced briefing information for the public on AIDS in Canada. It reported the three cases of AIDS in hemophilia patients in the U.S. and concluded that:

There is a theoretical risk that an unknown transmissible agent present in AHF products may be responsible for AIDS in these patients.<sup>540</sup>

359. While there were six reported cases of AIDS in Canada at this time, there was no report of any Canadian hemophiliac with AIDS.<sup>541</sup> Nevertheless, in September 1982, the

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*Ex. 847, Vol. 187, Tab 2 (Tsoukas, Christos et al "Immunological Dysfunction in Patients with Classic Hemophilia Treated with Lyophilized Factor VIII Concentrates and Cryoprecipitate", unpublished, circa 1983).*

<sup>537</sup> *Ex. 562, Tab 25, pp. 30-31 (July 19, 1983 Minutes of FDA Blood Products Advisory Committee Meeting).*

<sup>538</sup> *Evidence of Dr. Tsoukas, Montreal General Hospital, pp. 39659-39660.*

<sup>539</sup> *Ex. 562, Tab 25, p. 27 (July 19, 1983 Minutes of FDA Blood Products Advisory Committee Meeting).*

<sup>540</sup> *Ex. 614, Vol. 11, Tab 44, p. 1 (August 6, 1982 "Briefing Information - Acquired Immune Deficiency Syndrome in the United States and Canada").*

<sup>541</sup> *Ex. 614, Vol. 11, Tab 46 (August 13, 1982 Memorandum from Dr. Derrick to File).*



CRCS Immunology/Virology Working Group met and addressed the possibility that hemophiliacs might be at risk for AIDS. Considering the Canadian AIDS statistics and the lack of cases in hemophiliacs, the group was of the opinion that the evidence that hemophiliacs were at risk for developing AIDS was inconclusive.<sup>542</sup>

360. This view was echoed throughout the blood banking community. The same month Dr. Derrick attended a meeting of the Plasma Derivatives Advisory Committee of AmCross in Washington, D.C.. At the meeting, Dr. Roger Dodd, Head of Transmissible Disease and Immunology at AmCross, stated that AmCross was not taking an active position on AIDS since, "it is felt that evidence of a direct or causative involvement of blood products in the development of the syndrome is very slim." Of the three hemophiliac cases which had been reported in the *MMWR*, one had since been ruled out as a case of AIDS, and no new cases had been verified.<sup>543</sup>

361. On September 27, 1982, representatives of the LCDC, the BoB, the CHS and the CRCS met in Ottawa at the LCDC to discuss the occurrence and reporting of cases of AIDS. Dr. Strawczynski, Chair of the CHS MSAC, reviewed the perceived risk to hemophiliacs. She stated her uncertainty regarding the significance of the three *MMWR* cases in determining whether hemophiliacs were at higher risk for contracting AIDS. Reports of possible cases involving hemophilia patients in Montreal and Toronto had been sent to the LCDC and the CDC.<sup>544</sup>

362. Physician members of the American NHF MSAC and Canadian CHS MSAC became actively involved in the issue and deemed that more surveillance was necessary to

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<sup>542</sup> *Ex. 615, Vol. 12, Tab 7, p. 7 (September 9, 1982 Minutes of the Immunology/Virology BTS Working Group).*

<sup>543</sup> *Ex. 615, Vol. 12, Tab 12 (September 17, 1982 Trip Report by Dr. Derrick).*

<sup>544</sup> *Ex. 615, Vol. 12, Tab 13 (September 27, 1982 Trip Report by Dr. Derrick).*



determine whether these cases fit into the disease pattern<sup>545</sup>. The number of hemophiliacs who had been exposed to pooled blood products in contrast to the fact that only three hemophiliacs had developed AIDS seemed to indicate a low risk.<sup>546</sup> As of November 1982, hemophilia patients constituted only 0.3 per cent of all reported U.S. cases. The vast majority of cases of AIDS were observed in gay men.<sup>547</sup> On December 10, 1982, the *MMWR* reported four further cases of American hemophiliacs developing opportunistic infections. Nonetheless, the risk to hemophiliacs was still considered to be low.<sup>548</sup>

363. On January 4, 1983, American bloodbankers, scientists from the CDC and other parties to the U.S. blood system assembled in Atlanta to address the possibility that AIDS could be transmitted by blood and blood products.<sup>549</sup> Among the assembled group of bloodbankers and hemophilia treaters, there was no consensus as to whether AIDS posed a risk to hemophiliacs.

364. In February 1983 edition of *Transfusion*, Dr. Gerry Growe, Director of the Vancouver Hemophilia Assessment Clinic, reported the suggestion that hemophiliacs might be at risk for developing opportunistic infections. He provided an assurance that any risk was minimal:

It has been suggested that people who use intravenous medications such as drug addicts or people who are frequently transfused may fall into this category and there have been several cases in hemophiliacs described. But in all of North America we know of only four cases and it is not at all certain that they really reflect this condition.

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<sup>545</sup> Ex. 553, Vol. 127, Tab 19 (*Hemophilia Newsnotes Medical Bulletin* #2 - AIDS, July 30, 1982).

<sup>546</sup> Ex. 751, Vol. 158, Tab 52, p. 178 (October 4, 1982 Trip Report by Dr. Derrick re: Attendance at Ad Hoc Group Meeting at LCDC, Ottawa on September 27, 1982).

<sup>547</sup> Ex. 615, Vol. 12, Tab 23 (November 15, 1982 BTS Advisory Committee Meeting).

<sup>548</sup> Ex. 549, Vol. 124, Tab 44 (*MMWR* "Update on Acquired Immune Deficiency Syndrome (AIDS) among Patients with Hemophilia A." December 10, 1982).

<sup>549</sup> Ex. 554, Vol. 128, Part I, Tab 2, pp. 2-23 (January 4, 1983 Minutes of CDC - Dr. Man Chiu Poon, who would later work in Western Canada as a hemophilia treater and part-time CRCS Medical Director, attended from the University of Atlanta in his capacity as a hemophilia physician).



We write you this note mainly to reassure you that we have not seen any cases in British Columbia and in fact only two have been reported in Canada. We do not think that the hemophiliacs in this province are particularly prone to any unusual infections and have not seen it here.<sup>550</sup>

365. On February 7, 1983, the CHS MSAC met to consider whether hemophiliacs were at risk for developing AIDS and was to devise recommendations to reduce the potential risk of AIDS to hemophiliacs. The MSAC was greatly concerned about what they perceived to be the sensationalism the media had generated about the AIDS issue. These reports were upsetting to hemophiliacs, "even though there is not one confirmed case in Canada."<sup>551</sup> Consequently, the CHS issued a press release, which reflected the state of scientific knowledge and the perception of the risk at the time:

To date, there are no confirmed cases of AIDS in the Canadian hemophilia population, and it appears to be a very low incidence disease.<sup>552</sup>  
[Emphasis in original.]

366. Nonetheless, hemophilia experts advised that caution was warranted in relation to concentrate use regardless of whether AIDS was caused by an agent transmitted in pooled concentrates, multiple antigenic exposure or something else. Accordingly, in March 1983, the CHS MSAC issued guidelines on the use of cryoprecipitate and concentrate. The guidelines advised that patients who had never been treated with concentrates, those newly diagnosed and those treated mainly with cryoprecipitate who required concentrates for special circumstances, such as travel or surgery should be treated with concentrates manufactured from Canadian source plasma "wherever possible".<sup>553</sup> It was suggested that elective surgery should be cancelled and, in Ontario for example, children were to preferentially receive concentrates made from Canadian

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<sup>550</sup> Ex. 752, Vol. 159, Part 1, Tab 28, p. 2 (Transfusion, CHS, British Columbia Chapter, February, 1983).

<sup>551</sup> Ex. 752, Vol. 159, Part 1, Tab 36, p. 3 (February 7, 1983 Minutes of MSAC Meeting).

<sup>552</sup> Ex. 752, Vol. 159, Part 1, Tab 38 (February 8, 1983 Press Release).

<sup>553</sup> Ex. 752, Vol. 159, Part 1, Tab 39 (February 1983 Newsletter from CHS MSAC).



blood plasma.<sup>554</sup> However, the guidelines stressed that the cause of AIDS was not known, there was still no proof that AIDS could be transmitted by blood products, and that hemophiliacs should not stop treating bleeds.<sup>555</sup>

367. The May 1983 edition of *Hemophilia Ontario* reported that, of the 30 cases of AIDS reported in Canada to date, none were in hemophiliacs and none had been linked to component transfusion.<sup>556</sup>

368. Over the summer of 1983, the Toronto Department of Public Health distributed a pamphlet which emphasized that the health risk of not using Factor VIII concentrates or cryoprecipitate when required was greater than the risk of AIDS. In a June 27, 1983 draft of answers to potential media questions on AIDS, Bill Mindell of the Toronto Public Health Department wrote:

Hemophiliacs should be reminded that the health risk of not using Factor VIII concentrates or cryoprecipitate when it is required is much greater than the risk of getting AIDS. At present the risk for hemophiliacs appear to be about 1 per thousand in Canada...<sup>557</sup> <sup>558</sup>

369. In both the United States and in Canada physicians and public health officials were greatly concerned that many hemophiliacs in their panic about AIDS, had simply abandoned treatment with concentrates, thereby risking the dangers of a serious bleed.<sup>559</sup>

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<sup>554</sup> Ex. 753, Vol. 159, Part II, Tab 17, p. 45 ("Medical Corner", *Hemophilia Newsletter*, March 12, 1983).

<sup>555</sup> Ex. 753, Vol. 159, Part II, Tab 23 (March 28, 1983 MSAC Report).

<sup>556</sup> Ex. 754, Vol. 160, Tab 31 (*Hemophilia Ontario*, June, 1983).

<sup>557</sup> Ex. 754, Vol. 160, Tab 42, pp. 182-183 (June 27, 1983 Memo to File by Bill Mindell).

<sup>558</sup> Evidence of Bill Mindell, CHS Member (Ontario Chapter), p. 32203.

<sup>559</sup> Evidence of Dr. Growe, Clinical Professor, Medicine/Pathology, University of British Columbia, pp. 33061-33064;

*Evidence of Dr. Shepherd, Head Section of Medical Oncology Division of Hematology/Oncology, The Toronto Hospital General and Western Divisions Hospital Branches, p. 25190; and*



370. In May 1983, the Ontario CHS MSAC published a Chapter Advisory on AIDS and hemophilia. The bulletin advised that the risk of life-threatening bleeding or crippling outweighed the risk associated with plasma derivative use. Dr. Herst, in her capacity as Chair of the Ontario CHS MSAC, wrote:

It is possible and not definitely proven that exposure to a greater number of blood donors increases the likelihood of developing AIDS (by increased exposure to AIDS agent or different proteins).<sup>560</sup>

371. That month, Dr. Louis Aledort, Chair of the NHF MSAC, addressed the national CHS MSAC meeting. He said that it was still debatable whether AIDS was transmissible and, if it was, he commented that the real relationship to transfusion was not understood. Dr. Aledort told CHS MSAC members that the proven benefit of treatment was still considered to outweigh the risks.<sup>561</sup>

372. Not all hemophiliacs reacted to reports about the risk of AIDS by ceasing treatment. Most decided that the benefits of continued use of concentrates outweighed the perceived low risk of AIDS. In the summer 1983 edition of *Hemophilia News Notes* (an American publication), Dr. Glenn Pierce, a hemophiliac who was an immunologist and internist, wrote an article entitled, *"The Risk of Acquired Immune Deficiency Syndrome: A Patient's Perspective"*, in which he stated:

...years ago some of our doctors warned us about hepatitis and told us we would all die from liver failure if we began using pooled lyophilized concentrates.

Today, some of our doctors are warning us about AIDS and telling us we may die from overwhelming infections if we continue using concentrates.

What would it mean to me if I gave up concentrates and switched to cryoprecipitate? It would mean hours, not minutes, before a bleed would be controlled. It would mean hives and chills with the infusion, and a small chance

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Ex. 754, Vol. 160, Tab 4 (April 29, 1983 Memo from Dr. Herst to Ontario Chapter CHS MSAC Members).

<sup>560</sup> Ex. 754, Vol. 160, Tab 5 (May, 1983 Notice from Dr. Herst re: Hemophilia and Acquired Immune Deficiency Syndrome (AIDS)).

<sup>561</sup> Ex. 754, Vol. 160, Tab 15, p. 46 (May 13, 1983 Agenda - MSAC meeting).



of a life-threatening anaphylactic reaction. It would mean hours, maybe even a day of missed work. It would mean a loss of freedom to fly to New York or even drive to Akron. It would mean uncertainty, insecurity, and increased anxiety, knowing the emotional price of a new bleeding episode. It would mean more crippling, arthritis, and pain in my future.<sup>562</sup>

Dr. Pierce recounted his attendance at an NHF Board meeting when the risks of concentrate therapy were canvassed and discussed with other NHF members:

I attended The National Hemophilia Foundation (NHF) semi-annual Board meeting last April and talked with some of the most successful hemophilic men in the country, all of whom carried lyophilized concentrates in their overnight bags. We argued the risk/benefit ratio of switching to cryoprecipitate or of avoiding treatment of bleeding episodes. In a rare moment of understanding for any large group of individuals, we were all in strong agreement: these men were not willing to compromise their successful life styles, given the currently understood low risk of acquiring AIDS. The Medical and Scientific Council (MASAC) to NHF, composed of the leading hemophilia treaters in the country, has continued to publicly advocate no change in treatment regimens for individuals presently using concentrates. They have also repeatedly warned of the consequences of inadequate or delayed treatment of bleeding episodes.<sup>563</sup>

373. On July 19, 1983, at the FDA BPAC meeting, one of the issues discussed was the procedural policy with respect to lots of concentrate from donors who later showed symptoms of AIDS. It was agreed that the risk of AIDS from blood products was considered to be low, even if AIDS was, in fact, linked to concentrate use:

It was very clear that confronted with this complex problem the Committee felt that a balance must be struck between theoretical risk of the product to recipients against the need for an uninterrupted supply of a life-sustaining therapy... Adding to the uncertainty with regard to the decision of whether to quarantine or recall a product lot, several Committee members and other participants expressed the opinion that the risk of AIDS from transfusion of plasma derivatives or use of AHF concentrate has not been definitely established. They cited the fact that nearly all the hemophiliacs with AIDS had used material from

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<sup>562</sup> Ex. 754, Vol. 160, Tab 28, p. 122 (Dr. Glenn F. Pierce, "The Risk of Acquired Immune Deficiency Syndrome: A Patient's Perspective." Hemophilia News Notes Summer 1983).

<sup>563</sup> *Ibid* at pp. 122-123.



different lots, and that many other hemophiliacs receiving these same lots had not developed AIDS...<sup>564</sup>

374. Dennis Donohue, Head of the Office of Biologics (hereinafter referred to as "OoB"), Blood Products Division, summarized the decision of the expert committee, in his a July 21, 1983 memo to John Petricciani, Director of the OoB:

The risk of transmitting AIDS to an individual hemophiliac from a specific lot of Factor VIII is very, very small if it exists... It is emphasized that all aspects of AIDS including the cause, method of transmission, predisposing factors and definition of the syndrome itself, are incompletely understood in spite of the extensive and intensive research activity focused upon these issues and the benefit from life-threatening or disabling hemorrhage far exceeds the risk of acquiring AIDS. (Emphasis added.)<sup>565</sup>

375. In August 1983, the NHF published an AIDS update entitled, "AIDS and Hemophilia: Questions and Answers." It suggested that the risk of a hemophiliac contracting AIDS was very small:

At the present time, only a small fraction of 1% of the estimated population of 20,000 hemophiliacs in the United States have contracted AIDS. While the number of hemophiliacs with AIDS has increased, the total number of cases is still relatively small in the total hemophiliac population.<sup>566</sup>

376. As of September 2, 1983, sixteen cases of AIDS had been reported in American hemophiliacs. Only two cases of AIDS had been reported in Canadian hemophiliacs. Dr. Derrick commented on these statistics:

These figures indicate hemophilia patients constitute the group at highest risk of developing AIDS (approximately 1:1000) but at the same time, it would appear that the rate of increase in reported cases in this group has slowed markedly

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<sup>564</sup> Ex. 566, Vol. 138, Tab 4, pp. 33-34 (July 19, 1983 FDA Blood Products Advisory Committee Summary Minutes).

<sup>565</sup> *Ibid* at p. 35.

<sup>566</sup> Ex. 555, Vol. 128, Part II, Tab 26, p. 147. (*Hemophilia Information Exchange: "AIDS Acquired Immune Deficiency Syndrome: Questions and Answers"*).



since the initial reports in 1982. The published North American incidence figures for this group have remained unchanged for close to six months.<sup>567</sup>

377. The fact that there were no new reports of AIDS in hemophiliacs at a time when the rate of reported AIDS cases in gay and Haitian patients was doubling every six months<sup>568</sup> led hemophiliac treaters to conclude that the epidemic was not spreading to hemophiliacs. In November 1983, Dr. Kasper, a respected hemophilia treater from Los Angeles, commented on AIDS and hemophiliacs in her publication, *The Hemophilia Bulletin*:

The number of victims of AIDS who have been hemophiliacs appears to have hit a plateau. The worst predictions, of a huge epidemic of AIDS amongst hemophiliacs, have not come true. Perhaps persons with hemophilia are in much better general health than active homosexuals, and are exposed to much smaller doses of the AIDS agent.<sup>569</sup>

378. In November 1983, Dr. Chris Tsoukas reported on the results of a one-year follow-up study of 34 Montreal hemophiliacs who had laboratory evidence of immune abnormalities. He stated that he was encouraged by, "the lack of AIDS in the hemophiliacs I studied - particularly in four who displayed persistent lymphadenopathy". While their lymph nodes continued to be swollen, fatigue and night sweats had subsequently "resolved":

I may be over optimistic, but I think that given the fact these people have now gone one year with our followup and have not developed full-blown AIDS, there must be a sub-population of individuals that either get sub-clinical infection and show abnormalities, or that show clinical signs of sickness but don't progress to the full disease, and there's a very small minority that goes on to develop AIDS, "...<sup>570</sup>

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<sup>567</sup> Ex. 755, Vol. 161, Tab 27, p. 52 (Memo from Dr. Derrick to Dr. Perrault).

<sup>568</sup> Ex. 555, Vol. 128, Part II, Tab 20, p. 115 (Presentation by Dr. Bruce Ewart, "Latest Findings on AIDS at the Centres for Disease Control").

<sup>569</sup> Ex. 755, Vol. 161, Tab 53, p. 140 (*The Hemophilia Bulletin*, November 1983).

<sup>570</sup> Ex. 551, Vol. 125, Part II, Tab 49 (T. Murray, "Hemophiliacs in study didn't develop AIDS." *The Medical Post*, November 1, 1983).



379. Therefore, the meaning of the cellular immune abnormalities observed in hemophiliacs was still considered inconclusive. In December 1983, Dr. Bruce Evatt of the CDC, reported:

...this kind of finding must be considered as non-specific and only suggests more indepth analysis should be undertaken.<sup>571</sup>

380. On January 24, 1984, the American NHF again reaffirmed its position that hemophiliacs should not change their present treatment regimes:

AND MOST IMPORTANT, DESPITE THE CONCERN THAT MAY BE RAISED BY THE RECALL OF PLASMA PRODUCTS, THE NHF RE-AFFIRMS ITS RECOMMENDATION THAT PATIENTS MAINTAIN THE USE OF CONCENTRATE, OR CRYOPRECIPITATE AS PRESCRIBED BY THEIR PHYSICIANS. THE LIFE AND HEALTH OF HEMOPHILIACS DEPENDS UPON THE APPROPRIATE USE OF BLOOD PRODUCTS.  
[capitals original]<sup>572</sup>

381. Gradually, the suggestion that hemophiliacs were at higher risk for developing AIDS than the normal population gained acceptance among experts and scientists. However, this risk was still perceived to be so low that it did not necessitate any major changes in the treatment of hemophilia. This opinion was held by experts in the treatment of hemophilia worldwide. In February 1984, the World Federation of Hemophiliacs (hereinafter referred to as "WFH") published a bulletin, which included a section on AIDS. The medical board of the WFH had advised the Council in General Assembly:

There is insufficient evidence to recommend at the present, any change in treatment; therefore present treatment of hemophilia should continue with whatever blood products are available, according to the judgment of the individual physician.<sup>573</sup>

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<sup>571</sup> Ex. 556, Vol. 129, Tab 71, p. 295 (December 14, 1984 Summary of ABC Board of Directors Meeting re: "Status of AIDS and Transfusion", by Bruce Evatt).

<sup>572</sup> Ex. 756, Vol. 162, Tab 11 (Hemophilia Information Exchange, AIDS Update, Medical Bulletin #10, Chapter Advisory #132, January 24, 1984).

<sup>573</sup> Ex. 756, Vol. 162, Tab 18, p. 66 (February 1984 World Federation of Hemophilia, Bulletin #21, New Quality of Life).



382. Similarly, in February 1984, Dr. Strawczynski, Chair of the CHS MSAC, revised the AIDS Update for publication in *Hemophilia Ontario*, an Ontario CHS Chapter bulletin. Dr. Strawczynski cautioned hemophiliacs on the dangers of inadequate treatment of haemorrhages and advised them to maintain their current blood therapy regimes. While the cause of AIDS was still unknown, Dr. Strawczynski noted that there was substantial evidence to suggest that AIDS might be transmitted by blood products. Nevertheless, the risk of developing AIDS from factor concentrates was still thought to be low:

The number of AIDS cases in the hemophilia population is very small. As of February 1984, there were 21 cases in the U.S.A., 2 in Canada and 6 in Europe. I am not aware of any new cases since then. The possibility of developing AIDS is still infinitely smaller than that of a life-threatening or crippling hemorrhage. The life and health of hemophiliacs depends upon judicial (sic) use of plasma products.<sup>574</sup>

383. In March 1984, *Hemophilia Ontario* published a special issue focusing on AIDS and hemophilia, which echoed Dr. Strawczynski's opinion:

The occurrence of AIDS in Canadian hemophiliacs is rare. Up until March of 1984, only 2 of the estimated 2000 hemophiliacs in Canada have been reported as having AIDS. The risk of a hemophiliac getting AIDS is much less than the risk of life-threatening or severely crippling bleeds due to inadequate transfusion of clotting factor to treat hemorrhages.<sup>575</sup>

384. On April 16, 1984, the *NHF Hemophilia Information Exchange* published a current AIDS Update. During the first quarter of 1984, the CDC had reported nine new cases of AIDS among hemophiliacs. There were now thirty-three hemophiliacs diagnosed with AIDS in the United States. However, the NHF was uncertain as to whether this established an upward trend:

This represents the largest number of cases in any single quarter since we first learned of AIDS in July 1982. Because of the small number base of

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<sup>574</sup> Ex. 756, Vol. 162, Tab 23, p. 91 (February 28, 1984 Letter from Mr. F. Terpstra to Dr. H. Strawczynski attaching "Update on AIDS").

<sup>575</sup> Ex. 756, Vol. 162, Tab 26, p. 95 ("Special Issue on AIDS", *Hemophilia Ontario*, March, 1984).



hemophiliacs, however, major fluctuations from one quarter to the next may occur without necessarily reflecting a new trend. A similar major fluctuation downward was experienced in the third quarter of 1983.<sup>576</sup>

385. In May 1984, Dr. Davey attended a Scientific Symposium in Washington, D.C. called, "Infection, Immunity and Blood Transfusion". Among the speakers was Dr. Francis, of the CDC, who presented a paper on AIDS and its relationship to retroviruses. The incidence of AIDS in American hemophiliacs was approximately 0.6 per 1,000 per year. It was not clear whether AIDS was more particularly related to cryoprecipitate or concentrate use.<sup>577</sup>

386. By the summer of 1984, the number of AIDS cases in hemophiliacs began to rise again. As of June 1, 1984, there were forty hemophiliacs diagnosed with AIDS in the U.S.. Three of those patients had other risk factors besides hemophilia.<sup>578</sup> In comparison, only two hemophiliacs in Canada had been diagnosed with AIDS.<sup>579</sup>

387. By the summer of 1984, a new, but complicated, laboratory HIV antibody screening test was available which allowed physicians to test hemophiliacs and other members of high-risk groups for antibody to the newly-discovered virus. On August 1, 1984, the NHF reported on the early results of HTLV-III/LAV antibody testing in a group of American hemophiliacs. However, knowledge about the meaning of the presence of antibody was not sufficiently advanced to allow physicians to give a prognosis to antibody positive patients:

As expected, the majority of hemophiliacs tested positive for HTLV-III/LAV antibodies. Testing positive for HTLV-III/LAV establishes the presence of

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<sup>576</sup> Ex. 757, Vol. 163, Tab 1 (Hemophilia Information Exchange - AIDS Update, April 16, 1984).

<sup>577</sup> Ex. 757, Vol. 163, Tab 16, p. 94 (May 9-11, 1984 Trip Report by Dr. Davey re: attendance at XVI Annual Scientific Symposium).

<sup>578</sup> Ex. 757, Vol. 163, Tab 36, p. 151 (WFH Publication, "AIDS Centre News", "Case Surveillance Report", July 1984).

<sup>579</sup> Ex. 552, Vol. 126, Tab 45 (May 18, 1984 "Update: AIDS in Canada", LCDC); and

Ex. 552, Vol. 126, Tab 47 (Based on May 18, 1984 and June 27, 1984, LCDC updates "AIDS in Canada").



antibodies against these agents, it does not suggest a diagnosis of AIDS. It is much too early at this time for any scientific conclusions to be derived from this new information.<sup>580</sup>[Emphasis original.]

388. At the Sixteenth International Congress of the World Federation of Hemophilia held in August 1984, there were a number of presentations on the incidence and nature of AIDS in the hemophiliac population. Dr. Arthur Bloom, a respected Welsh expert on hemophilia, stated that forty-five cases of AIDS had been reported in American hemophiliacs, which represented a frequency of four cases per thousand persons. In Europe, eleven cases had been reported in hemophiliacs, being a frequency of point eight per thousand persons.<sup>581</sup>

389. Dr. Aledort, Chair of the NHF MSAC, reported on the implications of AIDS for hemophilia therapy. He stated that the leading cause of death among hemophiliacs was still uncontrolled bleeding, which accounted for thirty-seven to fifty-eight per cent of reported causes of death. This was followed almost equally by the complications of liver disease and by suicide, each accounting for five to eight per cent of the reported causes of death of hemophiliacs. These figures, collected four years into the AIDS epidemic, led Dr. Aledort to conclude that:

The extent of the contribution to mortality among hemophiliacs caused by AIDS remains to be determined but will rank well down on the scale of major causes of death in this group of patients.<sup>582</sup>

Dr. Aledort predicted that, in hindsight, AIDS would be viewed as one of the complications that had to be overcome in the development of a therapy which would enable hemophiliacs to carry out increasingly productive and rewarding lives.<sup>583</sup>

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<sup>580</sup> Ex. 758, Vol. 164, Tab 1 (Hemophilia Information Exchange - AIDS Update, August 1, 1984).

<sup>581</sup> Ex. 758, Vol. 164, Tab 7, pp. 28-29 (August 24-28, 1984 Trip Report by Dr. Naylor re: attend XVI International Congress of the World Federation of Hemophilia).

<sup>582</sup> *Ibid* at p. 30.

<sup>583</sup> *Ibid* at p. 30.



390. On September 6, 1984, another AIDS Update bulletin was published by the NHF, which reaffirmed the position that hemophiliacs should not change their use of clotting factor or other treatment recommended by their physicians:

AND MOST IMPORTANT, DESPITE THE CONCERN THAT MAY BE RAISED BY THE RECALL OF PLASMA PRODUCTS, THE NHF RE-AFFIRMS ITS RECOMMENDATION THAT PATIENTS MAINTAIN THE USE OF CONCENTRATE, OR CRYOPRECIPITATE AS PRESCRIBED BY THEIR PHYSICIANS. THE LIFE AND HEALTH OF HEMOPHILIACS DEPENDS UPON THE APPROPRIATE USE OF BLOOD PRODUCTS.  
[Capitals Original]<sup>584</sup>

391. On October 13, 1984, the MSAC of the NHF revised its recommendations concerning AIDS and the treatment of hemophilia. In light of new evidence provided by the CDC on the results of heating of the HTLV-III virus, [discussed in the Heat Treatment section] the MSAC recommended that heat-treated concentrates should now be considered for use in hemophilia treatment, "with the understanding that the protection against AIDS is yet to be proven." The AIDS update reflected the prevailing uncertainty about what HTLV-III antibody test results conveyed about a person's prognosis:

Further, we do not know whether hemophiliacs who are positive for antibody to HTLV-III have been exposed to living virus capable of causing AIDS, or have developed effective immunity against AIDS.<sup>585</sup>

392. It was a commonly held view that the viral genetic information was "killed" during the process of lyophilization and, later, heat-treatment. Even though the virus was dead, the presence of the antigens still caused the immune system to produce antibody. Researchers had already determined that the number of AIDS cases in hemophiliacs was much lower than in gay men. This would help explain the apparent difference in the numbers of AIDS cases developing in gay men versus hemophiliacs. It was postulated that gay men might have been

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<sup>584</sup> Ex. 758, Vol. 164, Tab 8 (Hemophilia Information Exchange - AIDS Update, September 6, 1984).

<sup>585</sup> Ex. 758, Vol. 164, Tab 25 (Hemophilia Information Exchange - AIDS Update, October 13, 1984, p. 105).



infected with live virus and subsequently developed antibodies, whereas hemophiliacs might have been "vaccinated" by the disrupted virus found in concentrates.<sup>586</sup>

393. On November 20, 1984, the HPB issued briefing information on the Canadian federal position with respect to blood component transfusion and the administration of plasma derivatives to patients with hemophilia:

...the administration of blood products to patients with genetically acquired bleeding problems (haemophiliacs) obviously places recipients of these materials at risk of acquiring AIDS. The risk however is extremely low compared to other methods of transmission.<sup>587</sup>

394. From mid-1984 and throughout 1985, it was commonly asserted by hemophilia and infectious disease experts, that out of 100 people exposed to the HTLV-III virus, ten would go on to develop AIDS-related complex, while only one person would progress to full-blown AIDS.<sup>588</sup>

While the majority of persons with hemophilia have developed the HTLV-III antibody, less than 1 % have contracted AIDS. As of May 3, there were 73 persons with hemophilia and AIDS in the U.S. More encouraging, however, is the apparent stabilization (and perhaps declining) number of new cases appearing among people with hemophilia as reported in the attached May 3, 1985 CDC publication, Morbidity and Mortality Weekly Report (MMWR).<sup>589</sup>

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<sup>586</sup> Ex. 558, Vol. 131, Pt. 1, Tab 57, p. 220 (Gallo et al, "Development and Early Natural History of HTLV-III Antibodies in Persons with Hemophilia", Journal of American Medical Association, April 19, 1985).

<sup>587</sup> Ex. 999, Vol. 245, Tab 4 (Briefing Information: Canadian Position Regarding Blood Donation/Transfusion and the Relationship to the Risk of AIDS, dated November 20, 1984).

<sup>588</sup> Evidence of Dr. Johnston, former Director of Division of Epidemiology, Ministry of Health, B.C., p. 4333;

Evidence of Dr. Card, former President, CHS MSAC, pp. 31932-31933; and

Ex. 743, Tab 34 ("Risk Assessment and the Use of Factor VIII Concentrates During 1983-1985" by N.C. Hughes-Jones).

<sup>589</sup> Ex. 762, Vol. 168, Tab 25, p. 43 (Hemophilia Information Exchange - AIDS Update, May 17, 1985).



395. In January 1985, the WFH updated its members on the HTLV-III retrovirus and its relationship to AIDS. The total number of hemophilia patients who had developed AIDS was still considered small relative to the morbidity seen in other risk groups. The incidence rate was estimated at 3.6 cases per thousand for Factor VIII users, and 0.6 per thousand for Factor IX users.<sup>590</sup> As stated by Dr. Card, because the majority of scientists and physicians believed that "antibody" production conferred "immunity", the majority of "exposed" hemophiliacs would not develop AIDS:

...The discovery of the HTLV-III virus, which is associated with AIDS, and the fact that a majority of frequently treated hemophiliacs have converted to antibody positivity between 1978 and the present, has added new insight into the problems for hemophiliacs from this source. The evidence may indicate that the majority of hemophiliacs who are exposed to the virus may develop immunity (i.e. as with hepatitis B) with a small number (?incidence) developing the syndrome (sic)... [Emphasis Original.]<sup>591</sup>

396. Dr. Peter Levine, of the NHF MSAC, suggested in a 1985 paper on AIDS in hemophilia that hemophiliacs were more protected from developing full blown AIDS than gay men as they had received widespread "and probably repeated exposure to a more diluted (and possibly often killed) suspension of the virus." Universal exposure to the virus appeared to have occurred by the end of 1983, yet the attack rate of AIDS in hemophiliacs was not climbing steadily during reporting periods:

In addition, the last two reporting periods contained a disproportionate number of patients with mild and moderate disease. These observations suggest that there are a limited number of persons at risk for the clinical syndrome of AIDS. Further, the number of persons at risk for AIDS among those most likely to have been infected with HTLV-III virus (those with severe disease and frequent therapy) may be decreasing.<sup>592</sup>

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<sup>590</sup> Ex. 760, Vol. 166, Tab 1, p. 1 (*AIDS Centre News - HTLV-III Retrovirus Update*, Vol. 2, January, 1985).

<sup>591</sup> Ex. 760, Vol. 166, Tab 24, p. 80 (*Newsletter: Medical and Scientific Advisory Committee CHS*, February 4, 1985).

<sup>592</sup> Ex. 559, Vol. 131, Part II, Tab 59, p. 181 (P. Levine, "The Acquired Immunodeficiency Syndrome in Persons with Hemophilia", *Annals of Internal Medicine*, November 1985).



397. On May 23, 1985, Dr. Card wrote to Bob Shearer, President of the CHS, to update him on the risk of hemophiliacs developing AIDS. Using the NHF statistics, Dr. Card wrote:

The overall risk of AIDS in Canada is approximately 20 percent of the USA at the moment. Toronto, Vancouver and Montreal are the highest. Data in the USA indicates that the risk for severe hemophiliacs may have reached its peak and there have been two documented cases [in Canada - handwritten on original] in 2500 hemophiliacs (less than 0.1 percent). It should be pointed out that despite the recent development of AIDS cases in blood transfusion that the risk is less than one per million units transfused. The risk from a single-donor blood product such as cryoprecipitate in Canada would be approximately the same.<sup>593</sup>

398. The spring 1986 edition of *Hemophilia Ontario*, included an editorial on the risk of AIDS developing in antibody positive hemophiliacs:

For anyone who was exposed to this virus before these safeguards were put in place, the risk of developing A.I.D.S. also appears to be very low. A number of hemophiliacs have developed swollen lymph glands and other effects of the virus, but only two in Ontario have gone on to develop A.I.D.S.<sup>594</sup>

399. As more cases of AIDS appeared in antibody positive hemophiliacs and gay men, there was greater uncertainty about whether an antibody was, in fact, protective. Discrepancies in the rates of AIDS development between high-risk groups led some researchers to believe that certain groups such as gay men, might be at higher risk for developing AIDS than others, and that susceptibility to AIDS was related to whether someone was already in poor health or immune-compromised.<sup>595</sup> In the July 1996 *Hemophilia Bulletin*, Dr. Kasper reported that in the U.S. the incidence of AIDS in seropositive hemophiliacs was not increasing at the rapid rate it was in seropositive gay men:

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<sup>593</sup> Ex. 762, Vol. 168, Tab 35, (May 23, 1985 Letter from Dr. R. Card to Mr. B. Schaefer).

<sup>594</sup> Ex. 766, Vol. 172, Tab 12, p. 43 (*Hemophilia Ontario Newsletter*, CHS Ontario Chapter, Spring 1986).

<sup>595</sup> Evidence of Dr. William Cochrane, Chairman, C.E.O. Connaught 1978-1988, pp. 38313-38314.



The prevalence of seropositivity is over 90% in severe hemophilia A, and about half that in hemophilia B. Is the critical determinant duration of infection, as some believe? Or is there an element of resistance, perhaps immunization, in hemophiliacs?<sup>596</sup>

400. By 1987, some years into the North American AIDS epidemic, it was becoming evident that a very large number of people who were HIV antibody positive would, indeed, progress to AIDS. At the May 1, 1987 meeting of the Canadian Hemophilia Clinic Medical Directors, Dr. Tsoukas reported on the results of immune testing performed on hemophiliacs. He had observed a definite progression of HIV infection in the hemophiliacs he studied. A number of patients in the study had died.<sup>597</sup>

401. By the summer of 1987, the risk of those people who tested positive for the HIV antibody progressing to AIDS was becoming clearer. In the June 1987 edition of the *Hemophilia Bulletin*, Dr. Kasper reported that every three days, a new case of AIDS in an American hemophiliac was reported to the CDC:

Furthermore, projections of the percentage of seropositive persons likely to fall ill due to infection with HIV, the AIDS virus, is constantly increasing. Thus, a large proportion of persons with hemophilia, most of whom already are seropositive, are likely to become ill in the next few years -- how many and how soon we don't know, and, frankly, we hate to think about it.<sup>598</sup>

402. It was only over time that it was understood how AIDS progressed from initial infection to the ultimate failure of the immune system. The actual degree of risk hemophiliacs faced in using concentrates and plasma derivatives in the early and mid-1980s could not be understood until the course of this new disease was followed through from infection to morbidity to mortality. Although it was recognized relatively early that hemophiliacs were at risk of contracting AIDS, the risk was perceived to be smaller than the hazards of discontinuing

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<sup>596</sup> Ex. 766, Vol. 172, Tab 49, p. 241 (*The Hemophilia Bulletin*, July 1986).

<sup>597</sup> Ex. 769, Vol. 175, Tab 4, p. 24 (May 1, 1987 Meeting of Canadian Hemophilia Clinic Medical Directors Report by Dr. R. Card).

<sup>598</sup> Ex. 769, Vol. 175, Tab 16, p. 99 (*The Hemophilia Bulletin*, June 1987).



treatment. Moreover, it was not recognized that AIDS was invariably fatal until later in the epidemic - after blood products could be tested for the presence of the virus and heat-treated to destroy it.

(ii) . Risk of AIDS From Blood Transfusion

403. With the appearance of AIDS-like conditions in hemophiliacs reported in July 1982, questions were raised about whether blood component transfusions could lead to a similar breakdown of the immune system. Over the two years in which cases of AIDS had been reported, thousands of Americans had undergone component transfusions, but not one had developed AIDS. There was no evidence that routine blood transfusions posed any risk to a patient.<sup>599</sup>

404. A concern that ordinary blood transfusions could pose a risk for transmitting AIDS arose in December 1982. At that time, the CDC estimated the incubation of AIDS to be four to seven months.<sup>600</sup> The December 10, 1982 *MMWR* included a report of a San Francisco baby who had received blood components from a donor who subsequently died of AIDS. While the baby displayed opportunistic infections suggestive of AIDS, it was not reported as an official case, as the CDC definition did not include infants due to their underdeveloped immune systems. Accordingly, the "California Baby Case" sparked interest, but was by no means definitive evidence that AIDS could be spread by blood transfusion. It was but one transfusion out of millions of transfusions and involved an infant. Accordingly, the *MMWR* report was careful to

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<sup>599</sup> Ex. 549, Vol. 124, Tab 31 (J. Marx, "New Disease Baffles Medical Community." *Science* August 13, 1982).

<sup>600</sup> Ex. 553, Vol. 127, Tab 35, p. 139 (December 4, 1982 Summary Minutes: FDA Blood Products Advisory Committee Meeting #5 - "Workshop on the Evaluation of Stored Red Blood Cells").



note that this was not necessarily a case of AIDS and cautioned that "any interpretation of this infant's illness must be made with caution."<sup>601</sup>

405. Following the January 4, 1983 meeting in Atlanta, on January 13, 1983, the AABB, AmCross, and the CCBC issued a joint statement commenting on reports of AIDS and its possible links to transfusion. The figures set out in this joint statement were subsequently utilized in the "one-in-a-million" estimation the risk of AIDS by ordinary blood transfusion:

Fewer than 10 cases of AIDS with possible linkage to transfusion have been seen despite approximately 10 million transfusions per year.<sup>602</sup>

406. At the time this statement was made, there was uncertainty as to whether AIDS could develop as a result of infusion of blood components or concentrates. If it could be caused by infusion, the latency period from the time of infection to the expression of symptoms was theorized to be approximately six months with some theorists hypothesizing a latency period of up to two years.<sup>603</sup> This lengthy latency period was taken into consideration by the bloodbankers when the possible risk of AIDS as a result of blood transfusion was calculated as Dr. Zuck testified:

If you look at the time this document was written and the incubation period is published was somewhere between six months and two years and nobody was sure. It is ten million a year and we are now 1993, the epidemic started in '77, so you are talking about an appearance of ten cases over a five or six year period in which not ten million but closer to fifty million transfusions had been given. So you can argue about whether if -- it is two years, they all would have shown up by now, but it was widely believed that it was six months. Now we know it (sic) 12.2 years. But we didn't know that in 1983. So that is roughly where these calculations come from, and everybody did allow for the lag period that Don Francis referred to yesterday...

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<sup>601</sup> Ex. 549, Vol. 124, Tab 43, p. 156 ("Possible Transfusion-Associated Acquired Immune Deficiency Syndrome (AIDS) - California." MMWR December 10, 1982); and

*Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, p. 22351.*

<sup>602</sup> Ex. 554, Vol. 128, Part I, Tab 18, p. 119 (Memo from Kenneth Woods to CCBC Trustees).

<sup>603</sup> *Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22385-22387.*



And we did argue the lag period, or think about the lag period. We didn't think it was as long as it turned out to be.<sup>604</sup> (emphasis added)

407. The unknown long asymptomatic period following exposure led physicians and blood donors to believe that if AIDS was transmitted by blood, it was an extremely rare complication of blood transfusion. In the winter of 1983 there was no comprehension of the extent to which the virus had already infiltrated and infected the population. It was not yet known that AIDS had spread throughout whole portions of Africa, as only incidental reports of a similar disease in Zaire had been received.<sup>605</sup>

408. In March 1983, Dr. Dowdle of the CDC attended Connaught Laboratories and reported on the findings of an independent American scientific committee. The committee, working in concert with the CDC, had been struck to review the data on twelve suspected cases of transfusion-associated AIDS. The committee reported that six of the cases met the CDC definition for AIDS, while the other six were "left in suspense."<sup>606</sup> Confirmation of these six cases in which transfusion was the only risk factor, led Dr. Davey, among several others, to try to estimate the risk of developing AIDS following a blood transfusion in the United States. The total American population was 240,000,000. Three million patients received transfusions each year and a total of  $10^7$  units of red cells were transfused annually. Using these variables Dr. Davey calculated the incidence of transfusion-associated AIDS (hereinafter referred to as "TAA") in the United States at 1.5 per million.<sup>607</sup> This assessment of risk was widely held for some time thereafter.

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<sup>604</sup> Evidence of Dr. Zuck, former Director of Division of Blood and Blood Products, FDA, pp. 22386-22387.

<sup>605</sup> Evidence of Dr. Francis, Epidemiologist, pp. 21712-21713.

<sup>606</sup> Ex. 619, Vol. 16, Tab 9 (May 30, 1983 Memorandum from Dr. Davey to File).

<sup>607</sup> Ibid.



409. As of April 26, 1983, Canada had twenty-four reported cases of AIDS. There was only one case of AIDS reported in a hemophiliac and no cases of TAA.<sup>608</sup> The Canadian donor system was considered one of the finest in the world as it is based on an entirely volunteer donor base.<sup>609</sup> Moreover, rates of transfusion-associated disease were always significantly lower in Canada, in light of the much lower incidence of disease here and a healthier donor population. Accordingly, it was widely believed that if it was found that AIDS was transmissible through blood, the incidence of cases would be well below the incidence in the United States and the risk was extremely low.<sup>610</sup>

410. On April 30, 1983, the *Lancet* published a paper written by Dr. Ammann, which described the "California baby case", first reported in the December 10, 1982 *MMWR*. The baby had developed an AIDS-like illness after receiving blood components. This report highlighted the growing recognition of the latency period if AIDS was, indeed, an infectious disease and if the infant's illness was attributable to AIDS. In the Ammann case, the donor was healthy at the time of donation and did not manifest illness until seven months later. However, a transmissible agent was not the only possible explanation:

...Despite the known association of administration of blood products and transmission of infectious agents, there have been no reports of AIDS in transfused patients...

We believe that AIDS developed in this patient as a result of an infectious agent being transmitted by blood product administration; it is possible, however, that

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<sup>608</sup> Ex. 550, Vol. 125, Part I, Tab 35, p. 132 ("AIDS in Canada", March 31, 1983); and Ex. 550, Vol. 125, Part I, Tab 40 ("AIDS in Canada", April 26, 1983).

<sup>609</sup> Evidence of Dr. Francis A. Sheppard, Head Section of Medical Oncology Division of Haematology/Oncology, Toronto General Hospital, pp. 24633-24634; and Evidence of Dr. Fanning, HIV Inpatient Medical Director, Wellesley Hospital, pp. 2145-2146.

<sup>610</sup> Evidence of Dr. Sheppard, Head Section of Medical Oncology Division of Haematology/Oncology, Toronto General Hospital, pp. 24781-24782; and Dr. Turc, former Edmonton Centre Medical Director, pp. 7367-7369.



he was born with a primary immunodeficiency disorder which did not show clinical signs until 6 months of age.<sup>611</sup>

<sup>612</sup>

411. Meanwhile, the CDC was collecting and its consultants were reviewing all information on possible and suspected cases of TAA.<sup>613</sup> Their analysis indicated a lack of certainty as to the strength of the link between AIDS and blood transfusion. Relevant excerpts of the report are as follows:

Dr. Lew Barker commented:

At this point, there appears to be a small risk, overall, of AIDS transmitted by blood transfusion (larger for pooled plasma donors, specifically AHF).<sup>614</sup>

Dr. Bovie wrote:

The case review has been helpful and points up the great difficulty in reaching conclusions about the relationship between transfusion and AIDS. The best guess I can make is that there are a few cases where the relationship between transfusion and AIDS is strong. The number is small in adults and even smaller in children. The 2 children who are the most convincing had so much other disease that they are hard to evaluate.<sup>615</sup>

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<sup>611</sup> Ex. 550, Vol. 125, Pt. I, Tab 41, p. 958 ("Acquired Immunodeficiency in an Infant: Possible Transmission by means of Blood Products" by Anman Arthur J. et al in The Lancet, April 30, 1983).

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<sup>613</sup> Ex. 555, Vol. 128, Part II, Tab 27, p. 150 (August 23, 1983 Memo and Summary: Meeting of Consultants - AIDS and Blood and Blood Products, CDC, on May 12, 1983).

<sup>614</sup> *Ibid* at p. 152.

<sup>615</sup> *Ibid* at p. 153.



Dr. Hoyer wrote:

The review of data for PTA-AIDS has provided a much better overview of the likelihood that AIDS can be of consequence of blood transfusion. The aggregate of data clearly indicate a definite, though small risk.<sup>616</sup>

Dr. Hirsch reported:

The data presented pointed out the need for careful evaluation of each purported case of transfusion-AIDS. Several cases were inadequately studied or reported. The result is that one pediatric case and 2-4 adult cases are reasonably convincing; the others are other unconvincing or have insufficient data to make decisions.<sup>617</sup>

Dr. Stevens commented:

The hemophilia-associated cases are convincing but the "etiology" issues leave me wondering about the theory of immune-alteration susceptibility factors --... Thus, it is important to decide whether transfused agents (in AHF?) is causative, and that this phenomenological interpretation can be used to strengthen the "theory" of blood-transmitted AIDS.<sup>618</sup>

412. In June 1983, the CCBC, Amcross and the AABB, published a *Joint Statement on Directed Donations and AIDS* in response to reports of AIDS cases with transfusion as the only risk factor. It estimated that the risk of undergoing transfusion was still very low:

More than 10 million persons were transfused in the United States during the three-year period that these cases were reported and, therefore, it appears at this time that the risk of possible transfusion-associated AIDS is on the order of one case per million patients transfused.<sup>619</sup>

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<sup>616</sup> *Ibid* at p. 154.

<sup>617</sup> *Ibid* at p. 155.

<sup>618</sup> *Ibid* at p. 156.

<sup>619</sup> Ex. 619, Vol. 16, Tab 31 (*Joint Statement on Director Donations and AIDS*, dated June 22, 1983).



413. On June 22, 1983, William Miller, President of the ABC, published a statement on developing AIDS after blood transfusion. The CDC had reported fifteen cases of AIDS related to blood transfusion out of a total of 1,552 cases reported. Over the prior three years ten million individuals had received blood transfusion. Therefore, he estimated the individual risk of contracting AIDS through blood transfusion as about one in a million.<sup>620</sup>

414. As of June 5, 1983, there were still no reported Canadian cases of AIDS in which transfusion was the only risk factor.<sup>621</sup> However, that month, Dr. Guévin of the Montreal Red Cross Blood Centre, was contacted by Dr. Lapointe from Hospital St. Justine, who reported a case of a baby who had received an exchange transfusion at birth and had developed what appeared to be the signs and symptoms of AIDS.<sup>622</sup> The CRCS traced five of the donors involved in the transfusion and contacted each of them. One donor appeared "suspicious" and could have been a gay man. This information was forwarded to Dr. Jessamine of the LCDC.<sup>623</sup> However, the LCDC, like the CDC, did not include suspected AIDS cases in children in their AIDS statistics. Again, this was based on the fact that the immune system in infants was poorly understood; children could often be born with congenital immune deficiencies which could, in turn, be exacerbated by a number of procedures, including transfusion and exchange transfusion.<sup>624</sup> With the tools that were available in the early 1980s, it was difficult to distinguish between immune deficiencies in infants which were congenital with those which had been acquired such as AIDS.<sup>625</sup> Thus, it was difficult to determine whether an immune deficiency was acquired or inherited:

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<sup>620</sup> Ex. 555, Vol. 128, Part II, Tab 12, p. 81 (June 22, 1983 ABC Press Release: "A Message to American Blood Commission Members About AIDS and Transfusion from William V. Miller, MD, President").

<sup>621</sup> Ex. 550, Vol. 125, Part I, Tab 63 (Canadian Diseases Weekly Report, June 5, 1983).

<sup>622</sup> Ex. 383 (July 8, 1983 Memo to File by National Director re: Toronto Star article dated June 28, 1983).

<sup>623</sup> *Ibid* at p. 2.

<sup>624</sup> Ex. 554, Vol. 128, Part I, Tab 28, p. 166-167 (January 26, 1983 Memorandum from Mr. Katz American Red Cross re Enclosing Recommendations for Blood Donor Policies with Reference to Acquired Immune Deficiency Syndrome (AIDS)).

<sup>625</sup> *Evidence of Dr. Davey, former Assistant National Director BTS, pp. 29977-29979.*



...that CDC is currently not classifying children as AIDS patients "because current knowledge does not provide adequate definition of what is or is not normal immune function in very young children", it must be concluded that, unless Canadian authorities differ with this statement, there have been no cases of transfusion associated with AIDS cases reported in Canada to date.<sup>626</sup>

415. Therefore, there was still no reported case of TAA in Canada. As the federal authorities legitimately chose not to classify the Montreal case as a true case of transfusion-associated AIDS, the CRCS would not substitute its own definitions for those of the CDC in Atlanta and the LCDC in Ottawa.<sup>627</sup>

416. On August 1, 1983, Dr. Joseph Bove, Chair of the FDA BPAC, head of the AABB and Professor at Yale, cited the same level of risk at the Inter-Governmental Relations and Human Resources Committee on blood banking and AIDS.<sup>628</sup> He reported that each year some 10,880,079 units of blood were collected from volunteer donors and transfused into 3,271,792 recipients. Assuming these numbers were similar for 1981 to 1983, thirty million units of volunteer blood had been transfused since the advent of the AIDS epidemic:

In this vast experience the number of transfusion related cases is under 20. If - and there is no evidence yet that this is so -- but if all 20 cases under investigation by CDC finally turn out to be transfusion related, the incidence will be less than one in a million. We do not know that AIDS can be spread by transfusion, but that possibility cannot be discounted. But if AIDS can be spread by transfusion, what we know now suggests that the risk is minimal. Much less than the risk of many other well known and accepted risks associated with transfusion, with medical practice and with life itself.

[Emphasis Original]<sup>629</sup>

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<sup>626</sup> Ex. 621, Vol. 18, Tab 23, pp. 1-2 (September 27, 1983 Memorandum from Dr. Derrick to Dr. Perrault).

<sup>627</sup> Evidence of Dr. Perrault, former National Director BTS, pp. 29974-29977.

<sup>628</sup> Ex. 555, Vol. 128, Part II, Tab 24 (August 1, 1983 Statement: Joseph Bove on AIDS and Blood Transfusion before the Intergovernmental Relations and Human Resources Subcommittee of the Committee on Government Operations).

<sup>629</sup> Ibid at p. 137.



417. In the absence of corroborated cases of AIDS linked to blood transfusion, researchers had to rest their concerns regarding transfusions on the fact that the risk groups for AIDS were similar to that of hepatitis B. Dr. Johanna Pindyck of the Greater New York Blood Program, pointed out at a September 1983 IATC Working Group meeting, that "most of the evidence for blood borne transmission of AIDS does not relate to transfusion, but rather from epidemiological studies upon intravenous drugs abusers."<sup>630</sup>

418. From the scientific data available, it appeared that it might be possible to develop AIDS after blood transfusion. However, the extremely low incidence of the disease in transfused patients led researchers, including Dr. Francis of the CDC, to conclude that:<sup>631</sup>

...AIDS may be caused, at least, in part, by an infectious agent (3). Such an agent would presumably be transmitted only with great difficulty and in the case of intravenous drug abusers and hemophiliacs it could perhaps be transmitted by blood or blood products.<sup>632</sup>

419. One of the most puzzling aspects of AIDS in the early years was its effect on persons of Haitian origin.<sup>633</sup> The September 9, 1983 *MMWR* stated that the occurrence of AIDS among gay men, intravenous drug users, hemophiliacs, and sexual partners of members of these groups was consistent with the hypothesis that AIDS was caused by an agent that is transmissible through infected needles or blood.<sup>634</sup> The phenomenon of AIDS in Haitians may

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<sup>630</sup> *Ex. 555, Vol. 128, Part II, Tab 34, pp. 180-182 (September 14, 1983 Letter from Dr. Dodd to Dr. Jamieson/Ms. Harkness, ARC re: IATC Meeting September 6).*

<sup>631</sup> *Evidence of Dr. Michael Louis Rekart, Director of STD Clinic, B.C. Ministry of Health, pp. 5180-5182.*

<sup>632</sup> *Ex. 551, Vol. 125, Tab 33, p. 114 (Donald Francis et al., "Antibodies to Human T-Cell Leukaemia Virus Membrane Antigens and Hemophiliacs." *Science* September 9, 1983).*

<sup>633</sup> *Ex. 551, Vol. 125, Part II, Tab 22 ("AIDS Update", *ECHO* dated September 1983);*

*Ibid, Tab 43 ("Federal AIDS Committee Proceeding Cautiously", T. Murray and "Haemophilia Study Funded", *The Medical Post* dated October 18, 1983); and*

*Ibid, Tab 59 ("AIDS in Haitian Immigrants and in a Caucasian Woman Closely Associated with Haitians", M. Laverdiere, J. Tremblay, R. Lavalee, et al., *CMAJ*, dated December 1, 1983).*

<sup>634</sup> *Ex. 551, Vol. 125, Part II, Tab 31 ("Update: AIDS - United States", *MMWR* dated September 2, 1983).*



have lent credence to the various other hypotheses which were current to explain AIDS and the rise of opportunistic infection in particular groups until the announcement of the discovery of HTLV-III in April 1984.

420. As the number of reported cases of AIDS increased, there was no corresponding jump in cases in people with no other risk factor than transfusion. In December, 1983, the U.S. Federal Department of Health and Human Services, published a pamphlet entitled, *Facts About AIDS*. The pamphlet explained that fewer than twenty-four persons were "suspected" of contracting AIDS from blood transfusions, "and that most of these cases are still under investigation." The chance of contracting TAA was still estimated at less than 1 in a million in the U.S. The medical necessity of blood transfusions was believed to far outweigh the risk of developing AIDS from the transfusion.<sup>635</sup>

421. Many now contend that Dr. James Curran's study published in the January 12, 1984 *NEJM* definitively established a link between blood transfusion and AIDS.<sup>636</sup> The paper examined the results of an investigation of eighteen people who had received blood component transfusions and had later developed AIDS. A lookback was completed in seven cases. Eight high-risk donors identified by "history" or by "immunological evaluation" demonstrated lymphocyte abnormalities. However, none of the donors identified as high-risk actually had AIDS. In discussion, Dr. Curran wrote:

The current number of cases of AIDS associated with transfusion is small, representing about 1 percent of the reported cases of AIDS in the United States. These 18 cases were diagnosed during approximately 12 months, a period when over 3 million persons in the United States received transfusions.<sup>637</sup>

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<sup>635</sup> *Ex. 555, Vol. 128, Part II, Tab 49, p. 247 (December, 1983 DHSS Pamphlet: "Facts About AIDS").*

<sup>636</sup> *Ex. 552, Vol. 126, Tab 10 (Curran et al., "Acquired Immunodeficiency Syndrome (AIDS) Associated with Transfusions." The New England Journal of Medicine).*

<sup>637</sup> *Ibid at p. 55.*



422. Advance copies of this study were distributed within the scientific community. On December 16, 1983, Dr. Peter Tomasulo, President of the South Florida Blood Service, critiqued the study in the CCBC Newsletter. It was Dr. Tomasulo's view that there was still confusion surrounding whether it was possible to develop AIDS as a result of a blood transfusion. He pointed out some problems with the study. Some of the donors were classified as "suspicious" donors being members of a high-risk group. These donors, however, were not ill at the time of donation and none of them had gone on to develop AIDS. While donations had also been split into several components, the authors of the study had not traced the entire donation in order to ascertain whether the recipients of the other components had developed AIDS.<sup>638</sup> Dr. Tomasulo concluded that previous assessments of risk were not altered by this study:

We cannot dismiss the possibility that AIDS is transmitted by blood transfusion. This article contains no information indicating that our previous possible risk calculations are incorrect. However, we must counter public hysteria or overreaction that might be fueled by this study. This study does not prove that AIDS is transmitted by transfusion, and it does not prove that people receiving transfusions are at higher risk for AIDS than people not receiving transfusions. Public health would be jeopardized if patients and doctors became alarmed over the safety of transfusion, or if donors refrained from donating because of an unfounded fear of AIDS. [Emphasis Original]<sup>639</sup>

423. Dr. Bove, who wrote a comment about the Curran paper in the January 12, 1984 edition of the *NEJM*, agreed that the risk of developing AIDS as a result of transfusion was still considered to be "small". However, he concluded that Dr. Curran's data, although not perfect, were convincing enough to justify:

...listing AIDS among the rare but possible complications of receiving blood transfusions. Currently the number of cases of transfusion-related AIDS is extremely low, especially in relation to the over 3,200,000 persons given transfusions each year in the United States. Even if there is a striking increase

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<sup>638</sup> Ex. 623, Vol. 20, Tab 23, p. 9 (*CCBC Newsletter*, December 16/23, 1983).

<sup>639</sup> *Ibid* at p. 10.



in cases over the next year, AIDS will remain an extremely infrequent complication of transfusion.<sup>640</sup>

424. In the spring of 1984, the first federal Health and Welfare Canada pamphlet on AIDS was drafted by NAC AIDS. It stated that the risk of refusing a blood transfusion outweighed the risk of contracting AIDS.<sup>641</sup> The NAC AIDS authors estimated the risk of developing AIDS following blood transfusion at "about two in a million". This estimate of the risk was based on the number of cases of AIDS relative to the number of donations.<sup>642</sup>

425. Over the summer of 1984, Canada still appeared to be untouched by TAA. Each year in Canada, approximately 1.3 million units of blood were collected, separated into components and transfused into approximately three hundred thousand recipients. Nevertheless, there were no official cases of transfusion-associated AIDS in the country. The number of units produced and transfused into patients when considered in conjunction with the understanding of the latency period resulted in a risk estimate of TAA as one in a million.<sup>643</sup>

426. In a December 1984 *Lancet* editorial on blood transfusion, hemophilia and AIDS, the assessment of the risk of acquiring TAA was modified to one in one hundred thousand transfusions:

About 100 transfusion-associated cases have occurred in the USA, where some three to four million transfusions are given annually -- a risk over the past three years of about 1 in 100,000 transfusions.

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<sup>640</sup> Ex. 552, Vol. 126, Tab 12, p. 64 (J.R. Bove, "Transfusion-Associate AIDS - A Cause for Concern." New England Journal of Medicine January 12, 1984).

<sup>641</sup> Ex. 680, Vol. 144, Tab 56, p. 196 (December, 1984 Health and Welfare Canada Pamphlet "AIDS in Canada What You Should Know").

<sup>642</sup> Evidence of Dr. Clayton, NAC AIDS Panel, p. 41841.

<sup>643</sup> Evidence of Dr. Buskard, Clinical Professor of Medicine, University of British Columbia, pp. 5853-5855.



The chance of contracting AIDS from ordinary blood transfusion is therefore very small indeed and should become even less as donors are effectively screened.<sup>644</sup>

427. By January 1985, it was largely accepted that some cases of AIDS in the U.S. had been caused by blood transfusion. The risk, however, was considered to be extremely low as compared to the other risks inherent in surgery. Dr. Herbert Perkins of the Irwin Memorial Blood Bank wrote in the *American Journal of Haematology* that:

The evidence that AIDS can be transmitted by blood is now convincing, but we still need to ask what the risk is. The 75 blood recipients with AIDS come from a population of approximately 15,000,000 people transfused during the same period of time, a rate of one case of AIDS per 200,000 patients transfused. This is obviously a minimum rate, however, because the incubation period appears to extend at least up to 5 years and many transfused patients die of their original or an unrelated illness before the incubation period is over. Moreover, other patients are not considered to have AIDS because they have diseases or therapy that result in an acquired immunodeficiency. Even so, the risk of dying of AIDS following transfusion is far less than the risk of death from other complications (such as hepatitis), and only public concern, as expressed through the media, keeps transfusion-associated AIDS on the front pages.<sup>645</sup>

428. In the same month, the British Department of Health and Social Security issued a statement which was hoped to clear up any misunderstandings about the safety of blood transfusion following an English report of TAA:

Anyone who was advised to have a blood transfusion, or who had been given a transfusion, should not worry because the risk of getting contaminated blood was extremely small. Even if a person proved positive in the antibody screening test it did not mean that he or she would get AIDS. Only a very small proportion of people with positive results went on to have symptoms.<sup>646</sup>

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<sup>644</sup> Ex. 552, Vol. 126, Tab 94, p. 301 ("Blood Transfusion, Haemophilia, and AIDS", *The Lancet* December 22/29, 1984).

<sup>645</sup> Ex. 558, Vol. 131, Part I, Tab 5, p. 57 (H.A. Perkins, "Transfusion-Associated AIDS." *American Journal of Hematology* 1985).

<sup>646</sup> Ex. 558, Vol. 131, Part I, Tab 7 ("Blood Donations and AIDS: Statement from Department of Health". *The Lancet* January 5, 1985).



429. According to the January 8, 1985 LCDC Update on "AIDS" in Canada, there were, as yet, no official cases of AIDS linked to transfusion.<sup>647</sup>

430. In March 1985, the U.S. Department of Health and Human Services published an update on AIDS in Europe. As elsewhere in the world, AIDS did not appear to be spreading via transfusion. The risk in Europe, as in America, appeared extremely low. Of the 162 cases of AIDS seen in Europe, eight cases involved persons who had received transfusions and had no other apparent risk factors.<sup>648</sup>

431. By the end of March 1985, the number of Canadian AIDS cases had risen to 196. Still, no established cases were attributable to component transfusion.<sup>649</sup> However, by April 19, 1985, the first Canadian case of transfusion-associated AIDS was reported by the LCDC.<sup>650</sup> There were a total of 220 cases of AIDS in Canada. A second case had been reported to the LCDC and was under investigation. Thus, by the end of May 1985, there were two official cases of AIDS contracted through blood transfusion in Canada.<sup>651</sup>

432. By July 4, 1985, the LCDC reported a total of 248 adult and 17 pediatric cases of AIDS in Canada. Two cases had occurred in blood transfusion recipients. There was now also the report of a Canadian infant, now listed separately, who had acquired AIDS through

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<sup>647</sup> Ex. 558, Vol. 131, Part I, Tab 8 ("Update: AIDS in Canada." LCDC January 8, 1985).

<sup>648</sup> Ex. 558, Vol. 131, Part I, Tab 48 ("Update: Acquired Immunodeficiency Syndrome - Europe", MMWR March 22, 1985).

<sup>649</sup> Ex. 558, Vol. 131, Part I, Tab 49 (March 25, 1985 "Update: AIDS in Canada"); and  
Ex. 558, Vol. 131, Part I, Tab 58 (April 19, 1985 "Classification of AIDS Cases").

<sup>650</sup> Ex. 558, Vol. 131, Part I, Tab 63 ("First Blood Transfusion AIDS Seen in Canada." The Medical Post April, 1985).

<sup>651</sup> *Ibid*; and

Ex. 558, Vol. 131, Part I, Tab 81, p. 283 ("Testing Donors for AIDS." Macleans May 27, 1985).



blood transfusion.<sup>652</sup> An infant case was not reported previously due to the CDC's policy of excluding infant cases from "AIDS" statistics.<sup>653</sup> By September 6, 1985, a total of 300 cases of AIDS had been reported in Canada. Of these, three cases, or one per cent, had been linked with component transfusion.<sup>654</sup> Thus, by December 1985, 386 cases of AIDS had been reported in Canada. Of these five or 1.3 per cent were found in blood transfusion recipients. The infant case continued to be listed separately.<sup>655</sup>

433. Over the course of 1985, the overall number of AIDS cases increased dramatically. Prior to the availability of widespread antibody testing it was not possible to determine how many people were infected with the HIV virus nor whether a person was in the asymptomatic carrier state until he or she developed AIDS. With the antibody test, researchers could measure, with a great deal of accuracy, the number of people who had been "exposed" to the virus and thus, might be carriers. The discovery of the HIV virus coupled with the development of the antibody test, was the key to enabling scientists to understand and comprehend the actual risk of contracting TAA. Development of the antibody test also effectively halted further transmission of HIV through the blood supply by screening out most donors who had contracted the virus.

8) Discovery of HTLV-III/LAV: More Questions Regarding Risk Unanswered<sup>656</sup>

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<sup>652</sup> Ex. 559, Vol. 131, Part II, Tab 2 ("Update: AIDS in Canada." LCDC July 4, 1985).

<sup>653</sup> Ex. 558, Vol. 131, Part I, Tab 63 ("First Blood Transfusion AIDS Seen in Canada." The Medical Post April 30, 1985); and

*Evidence of Dr. Gill, Director, Bureau of Microbiology, LCDC, p. 42221.*

<sup>654</sup> Ex. 559, Vol. 131, Part II, Tab 36, p. 84 ("Update: AIDS in Canada." LCDC September 6, 1985).

<sup>655</sup> Ex. 559, Vol. 131, Part II, Tab 69 ("Update: AIDS in Canada." LCDC December 2, 1985).

<sup>656</sup> A full discussion of the discovery of the HIV virus and subsequent antibody tests is canvassed more fully in the Testing Section of these submissions.



434. As was stated by Drs. Zuck and Eyster in their response to the Institute of Medicine Report entitled *HIV and the Blood Supply: an analysis of crisis decision-making*:

The full title of the report implies that it was clear in the early 1980's that, in fact, there was a crisis. It is stated that, by January 1983, epidemiologic evidence strongly suggested that blood and blood components transmitted AIDS. In fact, by January, 1983, the CDC had reported only one possible case of the transmission of AIDS by the transfusion of a fresh blood component. Further, by January 1984, fewer than 30 cases of transfusion-transmitted AIDS had been confirmed by the CDC. Balance against a denominator of millions of transfusion recipients since 1977, such a total left it unclear at that time that a medical 'crisis' was upon the nation. Thresholds triggering urgent public health service action had not been exceeded. It is frequently mentioned critically in the report that the blood service organizations estimated the incidence of transfusion-transmitted AIDS at one case per million transfusions. Yet this was the same risk estimated by the PHS as late as April 1984. Further, even though it was not possible to envision the scope of the tragedy, blood banks took measures to intercept risky donor as early as 1983.

435. On April 23, 1984, U.S. Secretary of Health, Margaret Heckler, and Dr. Gallo of the NCI, announced the discovery of the HTLV-III retrovirus. The presence of the virus in a person was highly correlative with the development of AIDS. Dr. Gallo reported that of blood samples taken from substantial numbers of patients diagnosed with AIDS and with "pre-AIDS", some 90% had antibody to this newly discovered virus.<sup>657</sup> However, little was understood about what was the significance of antibodies to the virus for prognosis. At the press conference, Dr. Gallo admitted that he did not know how long after exposure to the virus symptoms developed in a person.<sup>658</sup>

436. The discovery of the HIV virus provided a further evidentiary basis for the theory that AIDS was in fact a disease marked by a complex broad clinical spectrum of illness. Using

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<sup>657</sup> Ex. 552, Vol. 126, Tab 35 (*AABB News Briefs*, "Probable Cause of AIDS Identified." *Science* May 1984);

*Ibid*, Tab 37 ("Antibodies Reactive with Human T-Lymphotropic Retroviruses (HTLV-III) in the Serum of Patients with AIDS", May 4, 1985); and

Ex. 556, Vol. 129, Tab 35, pp. 143-144 (April 23, 1983 Transcript Press Conference).

<sup>658</sup> *Ibid* at pp. 147-148 (At the press conference, Dr. Gallo related CDC statistics which said that nine months was the average time between transfusion and development of AIDS.)



antibody testing researchers could now determine the number of people who had been "exposed" to the agent causative of AIDS. But the particular usefulness of such a test was unknown. As Dr. James Mason, Director of the CDC in Atlanta, stated at the April 23, 1984 Press Conference:

We've described AIDS as a fatal disease with certain characteristics. Now, with the kind of tests that Dr. Gallo has developed, we can begin to look at AIDS as a whole spectrum of disease, a disease that starts probably with an initial infection. It probably has pre-symptomatic phases. It probably then gets into a lymphadenopathy phase. And we have not even completely described the disease yet, because we haven't had the tests available to do so.

And building upon these things that have been reported today, we can begin to test populations of people to see who has antibodies, who does not have antibodies, when do those antibodies after exposure to such things as blood transfusions (sic), where can we trace back to the donor?

It just begins a whole series of miracles that occur as a result of these very basic reports that you've heard here today. We would hope that within a year or two, as we meet with you again that we are going to have much, much information that will enable us to control and prevent this horrible disease.<sup>659</sup>

437. The publication of results of the early antibody tests on hemophiliacs caused much alarm among hemophiliacs. Hemophilia treaters sought to reassure patients that the implications for prognosis of a positive antibody test were not known. The leading scientific theory at the time was that the majority of people who had been exposed to the HIV virus had developed antibodies and would not proceed to develop the disease.<sup>660</sup> On November 4, 1984, the *Knight Rider* news service reported that seventy to ninety per cent of hemophiliacs in the United States had been "infected" with AIDS. On November 5, 1984, the *Hemophilia Exchange AIDS Update* responded to what it called "misleading information":

NHF Medical Co-Director Peter H. Levine, MD, stated that this information, as edited, is "grossly misleading," and the way it was reported, in some places, "has caused a considerable amount of unnecessary alarm." ... Dr. Levine emphasized "that it is important to remember that testing positive for HTLV-

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<sup>659</sup> *Ibid.*, at p. 156.

<sup>660</sup> Ex. 761, Vol. 167, Tab 5, p. 18 (*Hemophilia Information Exchange - AIDS Update*, March 1985).



III/LAV establishes the presence of antibodies against these agents, it does not suggest a diagnosis of AIDS".<sup>661</sup> [Emphasis Original.]

438. Even after the U.S. announcements of the discovery of the virus, it was still that only a small minority of those infected would succumb to AIDS. People whose immune systems were "worn down" or who had underlying conditions would be "more prone to developing AIDS if exposed to the virus."<sup>662</sup> In 1985 Dr. Francis reported at the first AIDS conference on the results of the San Francisco clinic cohort study that only 6% of infected individuals had gone on to develop AIDS.<sup>663</sup> Therefore, a correct assessment of the risk of contracting AIDS from transfusion could not be made at the time with any certainty. It was not known whether the blood from an antibody positive person would transmit the virus to a recipient and, if so, whether the recipient would go on to develop AIDS.<sup>664</sup>

439. By July, 1984, the preliminary results from the first large-scale antibody testing program were published in the MMWR. The accompanying editorial stated that the high prevalence of antibodies among members of high-risk groups suggested that HTLV-III was the cause of AIDS but it supported the position that seroprevalence did not necessarily lead to full-blown AIDS:

...add further support to HTLV-III/LAV being the etiologic agent of AIDS. They further demonstrate that exposure to the virus is much more common than AIDS itself among populations with increased incidences of the disease. If AIDS follows the pattern of many other infectious diseases, host response to infection would be expected to range from subclinical to severe. Milder disease states for AIDS have been suspected, since the reported frequency of

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<sup>661</sup> *Ex. 759, Vol. 165, Tab 7 (Hemophilia Information Exchange - AIDS Update, November 5, 1984).*

<sup>662</sup> *Ex. 558, Vol. 131, Pt. I, Tab 95, p. 334 (J. Rowlands "AIDS, Most Antibody Carriers Infectious", Ontario Medicine).*

<sup>663</sup> *Evidence of Dr. Francis, Epidemiologist, pp. 22248-22249.*

<sup>664</sup> *Evidence of Dr. Clayton, NAC AIDS Panel, pp. 41641-41642;*

*Evidence of Dr. Sheppard, Head Section of Medical Oncology Division of Haematology/Oncology, Toronto Hospital General and Western Divisions Hospital Branches, p. 24893; and*

*Evidence of Dr. Mathias, NAC AIDS Panel, p. 25278.*



lymphadenopathy and immunologic abnormalities, conditions associated with AIDS, has also been high in these groups. These data, based on limited samples of high-risk groups, suggest the spectrum of response to infection with HTLV-III/LAV may be wide.<sup>665</sup>

440. The MMWR editorial also expressed concerns about the percentage of positive test results and commented on the uncertainty of how many of these positives were "false". A false-positive reaction could be caused by an infection with an antigenically related virus or factors in the test itself, which cause the antibody to react. Finding the frequency and the cause of false-positive tests was essential during testing trials, especially in populations:

...such as blood donors who belong to no known AIDS risk groups, where the prevalence of true infection with HTLV-III/LAV is expected to be very low."<sup>666</sup>

441. To suggest that the production of antibodies meant chronic infection was contrary to what was known about immunology at that time. Very few scientists understood retrovirology and HIV was radically different from any virus which had been previously studied.<sup>667</sup>

442. Dr. Gallo likened infection with HIV to rabies, describing the cause of the illness as a relatively slow infectious process "with the expression of symptoms close to the terminal decline of the patient".<sup>668</sup>

It is now believed that HTLV-III may be a 'slow' virus which exhibits antigenic drift and changes continuously after it infects its host. Therefore no sooner is antibody produced than it becomes 'obsolete'.<sup>669</sup>

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<sup>665</sup> Ex. 552, Vol. 126, Tab 54, p. 191 ("Antibodies to a Retrovirus Etiologically Associated with AIDS in Populations with Increased Incidence of the Syndrome." MMWR July 13, 1984).

<sup>666</sup> *Ibid.*

<sup>667</sup> Evidence of Dr. O'Shaughnessy, Head of Human Retrovirology Laboratory, LCDC, p. 42078.

<sup>668</sup> Ex. 997, Vol. 243, Tab 51 (August 27, 1984 Memorandum from Dr. Clayton to Dr. Liston).

<sup>669</sup> Ex. 558, Vol. 131, Part I, Tab 95, p. 334 (J. Rowlands, "AIDS, Most antibody carriers infectious." Ontario Medicine).



443. In March 1985, NAC AIDS published an AIDS update in the *CDWR*, which read:

Isolation of HTLV-III from patients with AIDS and its associated states has resulted in a clearer -- but still incomplete -- understanding of the full spectrum of this disease and the cause of the underlying immunodeficiency.<sup>670</sup>

444. In the April 1985 edition of the *JAMA*, Dr. Elaine Eyster (with James Goedert and Robert Gallo) wrote:

The exact natural history of HTLV-III infection will not be known until several more years have elapsed. Current data suggest that HTLV-III infection probably does not lead to inevitable AIDS in most patients. The cumulative incidence of AIDS in homosexual men with HTLV-III antibodies is only on the order of 5% to 20%...the cumulative incidence of AIDS and AIDS-like illnesses, during more than three years of observation, has been lower, on the order of 2% to 4%.<sup>671</sup>

445. In the June 1985 edition of the *JAMA*, Drs. Dale Lawrence and Bruce Evatt, both from the CDC, reported on their participation in a study which revealed that in mid-1985 the meaning of a positive antibody test was still no clearer. It was posited that an antibody positive person might have been infected with, and been immunologically damaged by, the AIDS-associated viruses. However, a second class of antibody positive people might be those who had been able to control this infection immunologically. It was hypothesized that a third group who tested positive might exist consisting of those who had been effectively immunized perhaps by incomplete virus in factor concentrates, and were thus immunologically normal.<sup>672</sup> The following analogy is particularly apt in this regard to explain the confusion:

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<sup>670</sup> Ex. 685, Vol. 149, Tab 12, p. 103 (*Canada Diseases Weekly Report*, March 1985).

<sup>671</sup> Ex. 558, Vol. 131, Part I, Tab 57, p. 220 (Gallo et al., "Development and Early Natural History of HTLV-III Antibodies in Persons with Hemophilia." *Journal of American Medical Association* April 19, 1985).

<sup>672</sup> Ex. 558, Vol. 131, Part I, Tab 91, p. 327 (J. Jason et al., "Human T-Lymphotropic Retrovirus Type III/Lymphadenopathy-Associated Virus Antibody." *Journal of American Medical Association* June 21, 1985).



The detection of antibodies is very much like the discovery of jimmy marks on a door: you know that someone tried to get in, but you don't know whether they succeeded or not, or, if they did, whether they stole anything of value.<sup>673</sup>

446. Therefore, whether a particular patient who tested antibody positive would succumb to AIDS or remain healthy was far from certain. However, even more uncertain than prognosis was whether someone who was antibody positive could transmit the virus to another.<sup>674</sup> The question was whether AIDS was like Hepatitis B and other diseases, in which the body eliminated the virus leaving behind antibodies to protect it from another infection. By late 1985, however, some researchers favoured a different interpretation of what a positive HTLV-III antibody result meant. Those who tested positive may not be in danger of developing AIDS, but were, at the very least, infectious:

Until recently it was believed that most individuals with antibody were not infectious.

But evidence is now mounting that the majority of people who test positive for AIDS...in fact, carry the virus are potentially infectious...<sup>675</sup>

447. Until 1987 it was commonly believed that a majority of people exposed to HIV were immune and would not develop AIDS. The only question was whether that number was one per cent, half a per cent or up to ten per cent.<sup>676</sup> In March 1987, the National Academy of Science/Institute of Medicine Committee predicted that 25 per cent to 50 per cent of persons

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<sup>673</sup> Ex. 122, Vol. 50, Tab 26, p. 73 (Ken Popert, "Taking aim with an empty gun?" *The Body Politic* July, 1985).

<sup>674</sup> Ex. 558, Vol. 31, Part I, Tab 10, pp. 74-75 ("HTLV-III Testing of Donor Blood Imminent: Complex Issues Remain." *Journal of American Medical Association* January 11, 1985; and

*Evidence of Dr. O'Shaughnessy, Head of Human Retrovirology Laboratory, LCDC and Dr. Gill, Director, Bureau of Microbiology, LCDC, pp. 42067-42068.*

<sup>675</sup> Ex. 558, Vol. 131, Part I, Tab 95 (Joyce Rowlands, "AIDS: Most Antibody Carriers Infectious", *Ontario Medicine* June 24, 1985).

<sup>676</sup> *Evidence of Dr. Davey, former Assistant National Director BTS, p. 30756.*



would develop AIDS within five to ten years of acquiring an HIV infection.<sup>677</sup> However, this Committee offered the warning that an even higher percentage progressing to AIDS after ten years could not be ruled out with the available data.<sup>678</sup>

448. By mid-1987 scientists had an opportunity to observe the course of infection with HIV virus over a longer period of time. As a consequence, it was soon realized that the vast majority of those infected with HIV would indeed go on to develop clinical illness. In April, 1987 at a meeting of the Medical Scientific Public Health Issues Committee of the Ontario Hemophilia Society, new information on AIDS progression was presented:

Studies are showing stronger evidence of AIDS progression ... within 7 to 10 years 80 to 90% are progressing to ARC or full blown AIDS... originally it was thought hemophiliacs might have formed a neutralizing antibody but (sic) more and more hemophiliacs are going on to ARC or AIDS...<sup>679</sup>

449. There are still numerous unanswered questions about the nature of HIV and its impact on the immune system. Research into AIDS and HIV has been immensely frustrating. Despite the optimism conveyed by US HHS Secretary Margaret Heckler when she announced the discovery of HTLV-III in April 1984 and predicted a vaccine in two years, after fifteen years following the very notion of the syndrome, many researchers have concluded that a truly effective vaccine against HIV can never be developed. Eleven years after the discovery of the virus, there is no explanation, although there are theories, as to how precisely HIV disables the immune system and leaves people open to opportunistic infection. It is still not known what proportion of people infected with HIV will experience the disability of their immune system. There is now evidence that some people may in fact have developed immunity to the virus or

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<sup>677</sup> Ex. 562, Tab 37, p. 1359 (Donald Francis and James Chin, "The Prevention of Acquired Immuno Deficiency Syndrome in the United States." Journal of American Medical Association March 13, 1987, Vol. 257, No. 10).

<sup>678</sup> *Ibid* at p. 1359.

<sup>679</sup> Ex. 768, Vol. 174, Tab 42, p. 119 (April 7, 1987 Minutes of the Meeting of the Medical Scientific Public Health Issue Committee).



will not develop AIDS.<sup>680</sup> Without a full record of the natural history of the disease, scientists must grasp at straws to predict a disease's cause and course. Often, based on the best available knowledge and the most sound scientific evidence, scientists predict incorrectly.<sup>681</sup>

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<sup>680</sup> *Evidence of Dr. Sheppard, Head Section of Medical Oncology Division of Hematology/Oncology, The Toronto Hospital General and Western Divisions Hospital Branches, pp. 25252-25253.*

<sup>681</sup> *Evidence of Dr. Clayton, NAC AIDS Panel, p. 41654.*













